Dissertation on

Prospective observational study

TO EVALUATE THE EFFICACY OF COLOUR DOPPLER IN DIAGNOSING ADNEXAL MASSES AT GOVERNMENT KILPAUK MEDICAL COLLEGE AND HOSPITAL, CHENNAI

Submitted to

The Tamil Nadu Dr. M.G.R. Medical University

In partial fulfillment of the requirements for the award of the degree of

M.D. DEGREE EXAMINATION

BRANCH – II (OBSTETRICS & GYNAECOLOGY)

KILPAUK MEDICAL COLLEGE

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

CHENNAI

APRIL 2014

BONAFIDE CERTIFICATE

Certified that the dissertation titled **"To evaluate the Efficacy of Colour Doppler in Diagnosing Adnexal Masses at Government Kilpauk Medical College and Hospital, Chennai"** is a bonafide work of the candidate **Dr.S.KALAIVANI,** post graduate student, Department of Obstetrics &Gynecology, Kilpauk Medical College, Chennai – 10, done under my guidance and supervision, in partial fulfillment of regulations of **TheTamilnadu Dr.MGR Medical University** for the award of **M.D.Degree Branch II, (Obstetrics & Gynecology)** during the academic period from May 2011 to April 2014.

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DECLARATION

I **Dr. S. KALAIVANI** solemnly declare that this dissertation titled **"To evaluate the Efficacy of Colour Doppler in Diagnosing Adnexal Masses at Government Kilpauk Medical College and Hospital"** was prepared by me at Government Kilpauk Medical College and Hospital, Chennai, under the guidance and supervision of **Prof. Dr.V. SUMATHI, M.D., D.G.O.,** Professor, Department of Obstetrics and Gynaecology, Govt. Kilpauk Medical College and Hospital, Chennai.

This dissertation is submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of the University regulations for the award of the degree of M.D. Branch II (Obstetrics and Gynecology).

Date: **Dr.S.KALAIVANI**

Place:

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Finally nothing is possible without the blessings of the omnipotent Almighty.

DR.S.KALAIVANI

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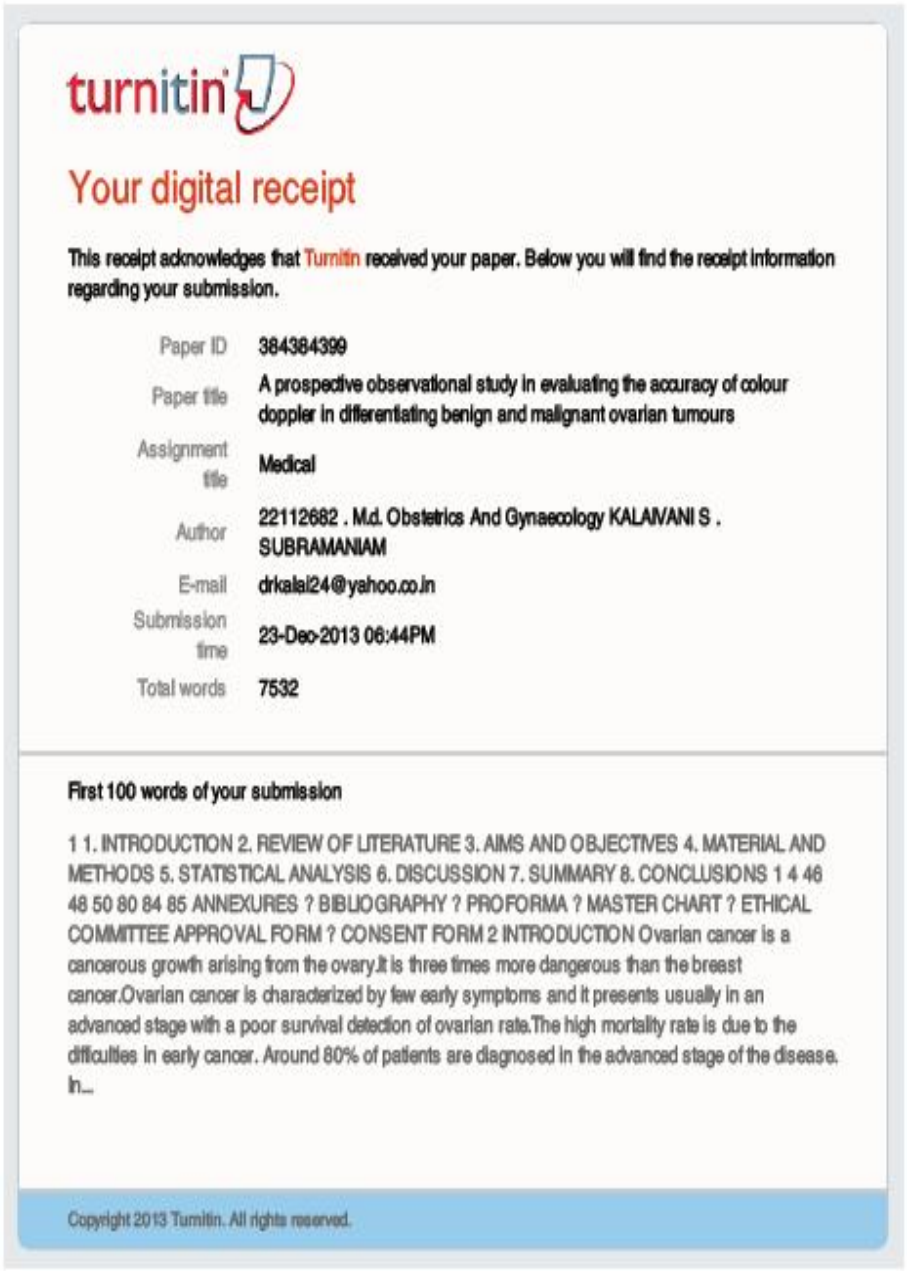

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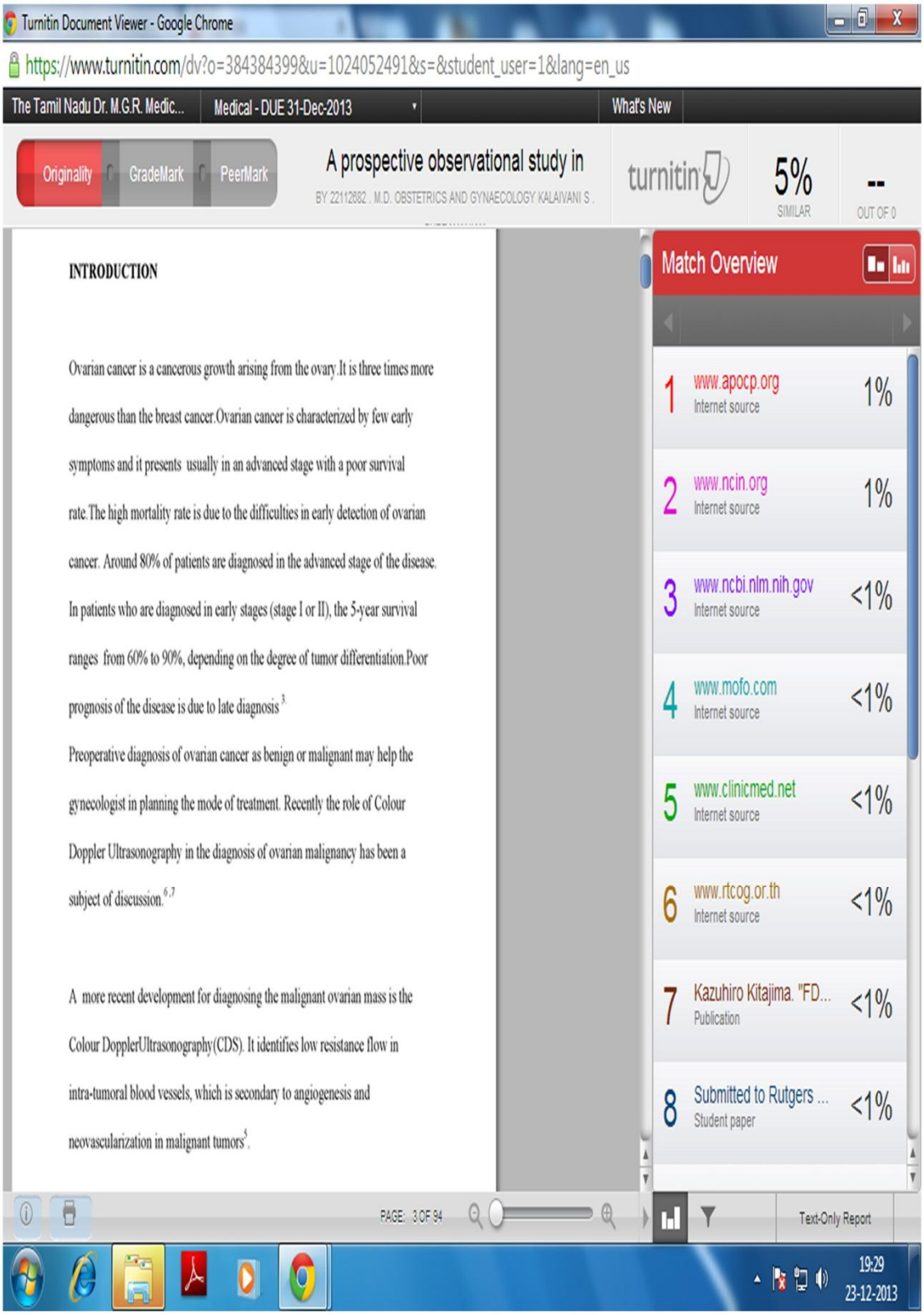
1 1. INTRODUCTION 2. REVIEW OF LITERATURE 3. AIMS AND OBJECTIVES 4. MATERIAL AND METHODS 5. STATISTICAL ANALYSIS 6. DISCUSSION 7. SUMMARY 8. CONCLUSIONS 1 4 46 48 50 80 84 85 ANNEXURES ? BIBLIOGRAPHY ? PROFORMA ? MASTER CHART ? ETHICAL COMMITTEE APPROVAL FORM ? CONSENT FORM 2 INTRODUCTION Ovarian cancer is a cancerous growth arising from the ovary.It is three times more dangerous than the breast cancer.Ovarian cancer is characterized by few early symptoms and it presents usually in an advanced stage with a poor survival detection of ovarian rate.The high mortality rate is due to the difficulties in early cancer. Around 80% of patients are diagnosed in the advanced stage of the disease. In...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INTRODUCTION
Ovarian cancer is a cancerous growth arising from the ovary.It is three times more dangerous than the breast cancer.Ovarian cancer is characterized by few early symptoms and it presents usually in an advanced stage with a poor survival rate.The high mortality rate is due to the difficulties in early detection of ovarian cancer. Around 80% of patients are diagnosed in the advanced stage of the disease. In patients who are diagnosed in early stages (stage I or II), the 5-year survival ranges from 60% to 90%, depending on the degree of tumor differentiation.Poor prognosis of the disease is due to late diagnosis[3].
Preoperative diagnosis of ovarian cancer as benign or malignant may help the gynecologist in planning the mode of treatment. Recently the role of Colour Doppler Ultrasonography in the diagnosis of ovarian malignancy has been a subject of discussion.[6,7]
A more recent development for diagnosing the malignant ovarian mass is the Colour DopplerUltrasonography(CDS). It identifies low resistance flow in intra-tumoral blood vessels, which is secondary to angiogenesis and neovascularization in malignant tumors[5].
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ABBREVIATIONS USED

CDS	-	Colour Doppler Ultrasonography
USG	-	Ultrasonography
CT	-	Computerized Tomography
RI	-	Resistive Index
PI	-	Pulsality Index
ROC	-	Receiver operative curve
AUC	-	Area under curve
HPE	-	Histopathology
PPV	-	Positive predictive value
ASR	-	Age standardized value
SEER	-	Surveillance epidemiology and end results
SONAR	-	sound navigation and ranging
AIUM	-	American institute of ultrasound in medicine
2D/3D	-	Dimension

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ABSTRACT

OBJECTIVE

To study the accuracy, sensitivity and specificity of Colour Doppler in differentiating Benign and Malignant ovarian tumours in 15-60 yrs age group patients attending Gynaecology Clinic at Government Kilpauk Medical College Hospital, Chennai.

STUDY DESIGN:

A Prospective observational study between January 2012 to September 2013 at Kilpauk Medical College Hospital, Chennai.

METHODS:

Women attending gynaecology clinic from 15-60yrs, who diagnosed to have significant adnexal mass are selected. All diagnostic modalities done including ultrasonography,ca125,colour Doppler calculating resistive and pulsality index are done. Finally results are compared with Histopathology

RESULTS:

75 patients are recruited .out of 75 patients, 15 are malignant and 60 are benign.

Ultrasonography has sensitivity and specificity **66.7%** and **81%** respectively

CT Abdomen and pelvis has sensitivity and specificity of **80%** and **85%** respectively

Ca125 has sensitivity and specificity of **66.67**% and **83.3**% respectively

Sensitivity and specificity of resistive index is**93.3%** and **86.7%** respectively

Area under curve is **0.922** which is statistically significant p value-**<0.0001.**

With the PI of **0.9** the sensitivity and specificity is **86.7% and 93.3%** respectively.With Receiver operative curve

Area under curve is **0.925** which is statistically significant p value**<0.0001**

Thus colour Doppler with high accuracy helps in early diagnosis for prompt traerment.

CONCLUSION:

Thus colour Doppler have high accuracy in differentiating benign and malignant ovarian tumours.

KEY WORDS:

Ovarian tumours Diagnosis, Resistive index, Pulsality index, Colour Doppler,

INTRODUCTION

Ovarian cancer is a cancerous growth arising from the ovary.It is **three** times more dangerous than the breast cancer.Ovarian cancer is characterized by few early symptoms and it presents usually in an advanced stage with a poor survival rate.The high mortality rate is due to the difficulties in early detection of ovarian cancer. Around 80% of patients are diagnosed in the advanced stage of the disease.

In patients who are diagnosed in early stages (stage I or II), the 5-year survival ranges from 60% to 90%, depending on the degree of tumor differentiation.Poor prognosis of the disease is due to late diagnosis [3.]

Preoperative diagnosis of ovarian cancer as benign or malignant may help the gynecologist in planning the mode of treatment. Recently the role of Colour Doppler Ultrasonography in the diagnosis of ovarian malignancy has been a subject of discussion.[6,7]

A more recent development for diagnosing the malignant ovarian mass is the **Colour Doppler Ultrasonography(CDS**). It identifies low resistance flow in intra-tumoral blood vessels, which is secondary to angiogenesis and neovascularization in malignant tumors[5].

This has been further discussed by several researches done by ***Bourne et al., 1989; Kurjak et al***., 1993; ***Rieck et al., 2006; Fleischer &Andreotti, 2005***).[12,23,25.]

By knowing the blood flow characteristics, one can predict whether the tumor is benign or malignant. Researchers have proposed Colour and Pulsed Doppler flow imaging as methods that may be useful in differentiating benign from malignant ovarian masses. According to the study based on ”**Folkman theory of neovascularisation**”, malignant neoplasms elaborate a factor called **Tumour angiogenesis factor**, which stimulates rapid formation of new capillaries[5].

I have chosen this topic because of the alarming increase in the incidence of malignant ovarian tumors in the last 20 years and ovarian malignancy is becoming an important cause of death in gynaeconcology.[34]

REVIEW OF LITERATURE

This is discussed under the following headings:

- INCIDENCE
- ANATOMY
- HISTOLOGY
- EMBRYOLOGY
- RISK FACTORS
- CLASSIFICATION OF OVARIAN TUMOURS
- HISTOLOGICAL TYPES OF EACH OVARIAN TUMOURS
    - INCIDENCE
    - MORPHOLOGY
    - HISTOLOGY
- DIAGNOSIS
    - ULTRASONOGRAPHY
    - CT ABDOMEN AND PELVIS
    - CA125
    - COLOUR DOPPLER ULTRASONOGRAPHY

INCIDENCE

The American Cancer Society estimates for ovarian cancer in the United States for **2013** are:

About **22,240** women will receive a new diagnosis of ovarian cancer.

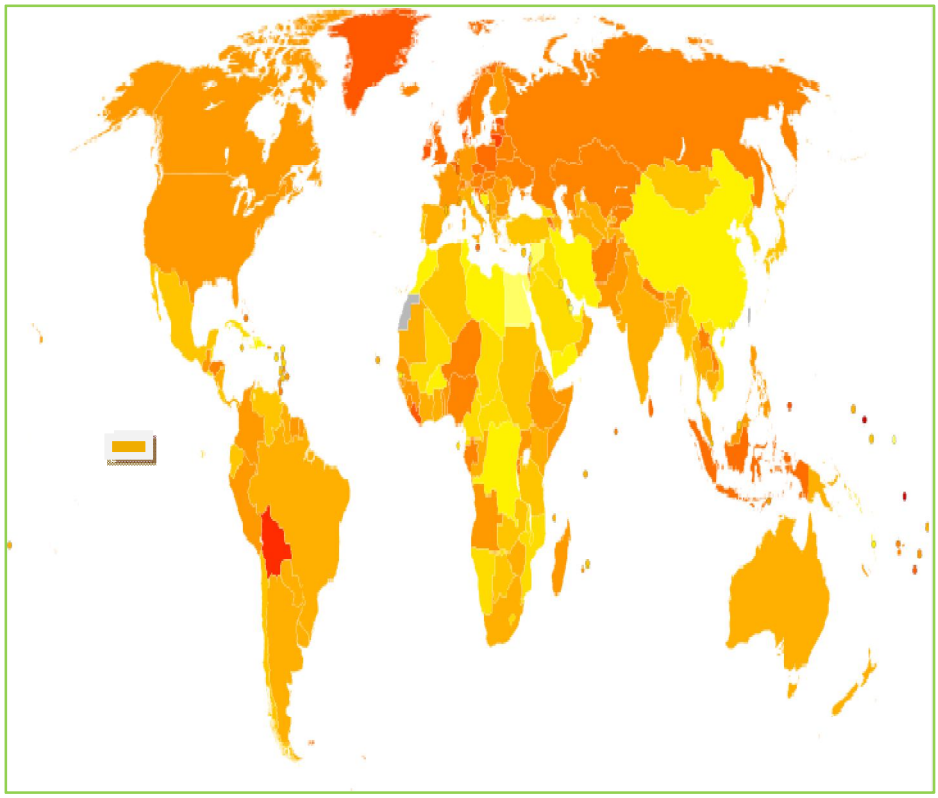
About **14,230** women will die from ovarian cancer.

Ovarian cancer ranks **fifth** in cancer deaths among women, accounting for more deaths than any other cancer of the female reproductive system. Ovarian cancer accounts for about 3% of all cancers in women.A woman's risk of getting ovarian cancer during her lifetime is about 1 in 72.Her lifetime chance of dying from ovarian cancer is about 1 in 100.The mean age at diagnosis is 63 yrs or older.

The incidence of ovarian cancer varies between the regions with the highest rates noted in **Europe** and **North America**. According to **SEER** cancer statistics rule published in June 2013 the number of new cases of ovarian tumour was 12.5 per 100,000 women per year. Incidence in Five Continents for various Indian registries found that during the period 2001-06, the **age-standardized incidence rates (ASR)** for ovarian cancer varied from 0.9 to 8.4 per 100,000 person years amongst various registries. Incidence of ovarian tumour in Asia is 5.1. In India the highest incidence noted in **Pune** and **Delhi** registries.

MAP SHOWING DEATH DUE TO OVARIAN CANCER

Worldwide distribution



High mortality **Low mortality**

ANATOMY

Ovaries are oval in shape and pinkish grey in colour. Each measures about 5cm in length,3cm in breadth and 3cm in thickness.

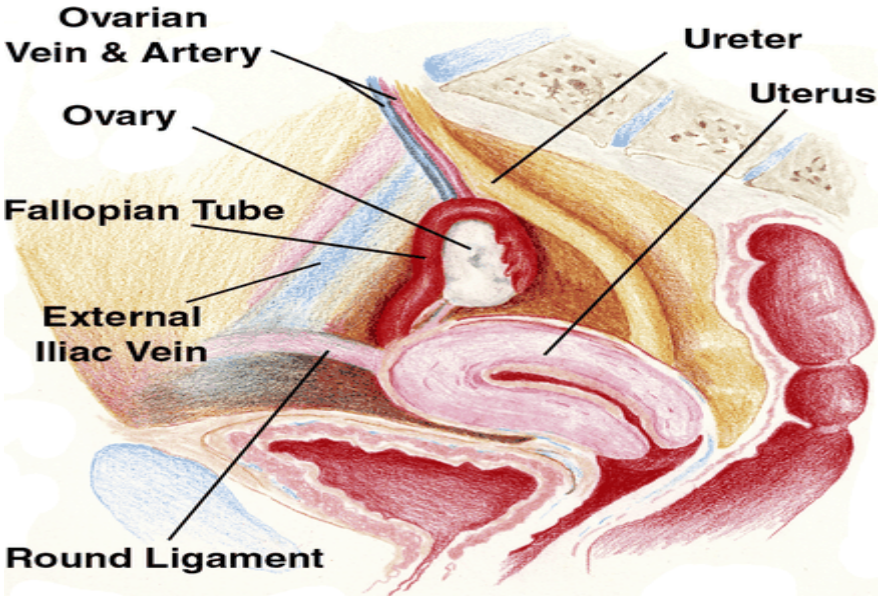


Figure: 1 shows the relationship of the ovary

OVARIAN FOSSA

Ovaries lies in ovarian fossa in lateral pelvic wall. It is related to external iliac vein superiorly, ureter and internal iliac vein posteriorly, peritoneum separating obturator vessels laterally.

HISTOLOGY

Ovary is lined by a single layer of cuboidal epithelium known as germinal epithelium. Substance of the gland consists of outer cortex and inner medulla.

CORTEX:

It consists of stromal cells which are thickened beneath the germinal epitheliu to form tunica albuginea.

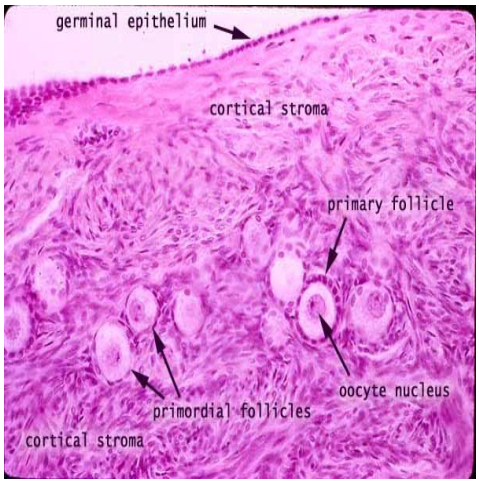


Figure 2:Histology of ovary

MEDULLA:

It consists of loose connective tissues,blood vessels and nerves.There are small collection of cells called hilus cells,which are homologous to the interstitial cells of testes.

EMBRYOLOGY

After 5th week of fertilization, two gonadal ridges develop on either side of the midline in the dorsal aspect of the embryo. These are formed by the proliferation of coelomic epithelium. The primodial germ cells are formed in the yolk sac and migrate along the mesentery of the hindgut into these gonadal ridges. These gonadal swelling differentiate into ovary or testis depending on the sex chromosome.

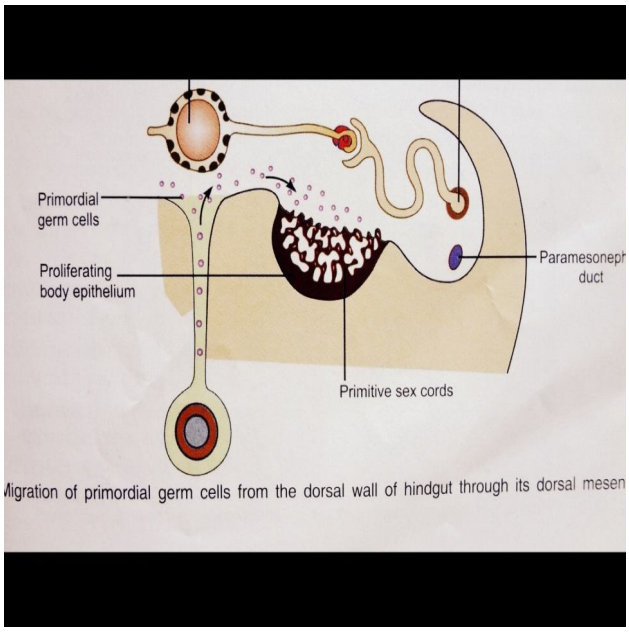


Figure 3 a:shows migration of primodial germ cells

BLOOD SUPPLY:

Arterial supply is from the ovarian artery, a branch of the abdominal aorta.Venous drainage is through the pampiniform plexus, which drain into inferior vena cava on right side and left renal vein on left side.

NERVE SUPPLY:

Sympathetic supply is from T10 segment, through the renal and aortic plexus.

PROTECTIVE FACTORS FOR OVARIAN TUMOURS:

Protective factors are oral contraceptive pills as described by (***Jensen A, Frederickson K***), Breast feeding (***yen 2003***), Retinoid, tubal sterilization (***Hankinson 1793***) and hysterectomy. Women who used oral contraception for 5 yrs or more have 50% reduction in the development of ovarian cancer. Prophylactic oopherectomy can be done in patients with high risk of ovarian cancer >35yrs[14]. It decreases the risk up to 90%.

RISK FACTORS

It occurs in age group of **56-60yrs**. In postmenopausal women, 30% are malignant, but in premenopausal women only 7% are malignant.Peak age for borderline tumours is 46 yrs. Hereditary ovarian tumours occur 10 yrs earlier than sporadic tumours.

Risk factors of ovarian tumor include

- Infertility (***Purdie 2003)***
- Low parity(***Hinkula 2006***)
- Early menarche
- Late menopause(***lancey 2006)***
- Failure to lactate
- Smoking
- Obesity
- Lack of exercise
- Talc on the perineum(***ness 2000)***
- History of endometriosis [3]
- Ovulation induction
- Diet rich in fat
- Familial factors

It has been estimated that life style contribute to **21%** of ovarian cancer.[35,37]It is estimated that 2% of cases may be caused by smoking.[36; 38.This] is also described by some researchers like ***Lurie G, Thompson PJ et al*** in 2013.

There is also evidence of increased risk in postmenopausal women who are overweight and who using dietary products as described by ***Faber MT, Hogdall C*** study in ***Danish (2012)***

Parity is inversely related to the incidence of ovarian cancer, having at least one child is protective with the ***reduction risk of 0.3-0.4%.***

Diet rich in animal fat and Ovulation Induction causing incessant ovulation has also been studied to be risk factors for ovarian cancer.

Familial patterns contribute to **5-10%** of the ovarian tumours.[8]

Most tumors are associated with germ line mutations in **BRCA1** mutation, smaller proportion by BRCA2 mutation. It follows autosomal dominant pattern of inheritance[4]. Family history of ovarian, breast, colon and endometrial cancer increases the risk of ovarian cancer. Having very close relatives with either ovarian cancer or breast cancer have 3-4 fold increase in developing ovarian cancer than any other women in the population.[9]

CLASSIFICATION OF OVARIAN TUMOURS

3 Main Tumours discussed in study are Epithelial tumour,Germ cell tumour,Sex cord stromal tumours.

EPITHELIAL OVARIAN TUMOURS

Approximately 90% of ovarian cancers are derived from tissues that come from the coelomic epithelium or mesothelium. About 70-80% of the ovarian tumours is of serous type. Overall, five-year survival in ovarian epithelial carcinoma is 35%.[33]

Classification by Histologic Type

- Serous -Endosalpingeal[70-80%]
- Mucinous –Endocervical[5]
- Endometrioid–Endometrial[10%]
- Clear-cell “mesonephroid” [5%]
- Brenner Transitional[<1%]
- Mixed epithelial
- Undifferentiated Anaplastic
- Unclassified Mesothelioma

TUMOURS OF SURFACE EPITHELIUM

SEROUS TUMOUR

INCIDENCE:

Serous cystadenoma is common in age group of **30-50yrs**. Malignant cystadenocarcinoma occur most often in advancing age **>50yrs**. In Bilateral presentation of the tumour 20% is benign where as 66% are malignant.

MORPHOLOGY:

Surfaces and loculi of the benign cyst contains papillary excrescences .In case of malignancy, coarse papillary growth is seen on the peritoneal surfaces. Papillae will be friable in malignant tumor.

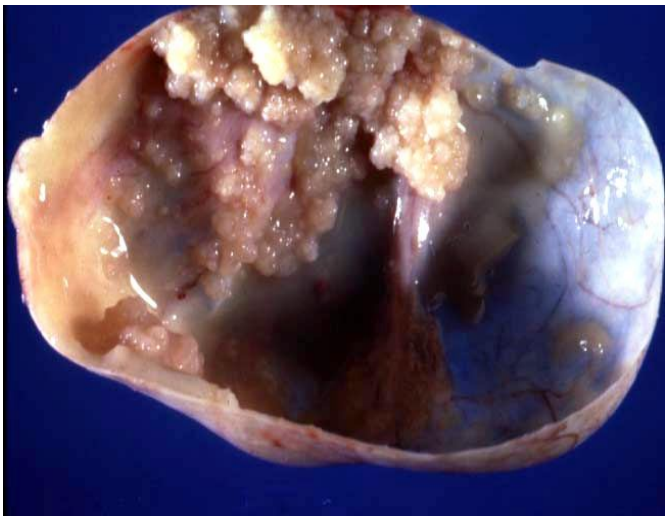


figure 4a:shows cut section of benign serous tumour with friable papillary excrescenses

Figure 4b &4c:shows papillary excrescences in malignant serous tumour

HISTOLOGY:

Benign cyst shows cystic spaces and is lined by tall columnar ciliated epithelium which resembles endosalpinx. Loculi contains serous straw coloured fluid. Psammoma bodies are seen frequently in this tumour. In malignant serous tumours there is increased complexity of papillae, stratification, increased nuclear atypia and stromal invasion. Fluid is often blood stained.

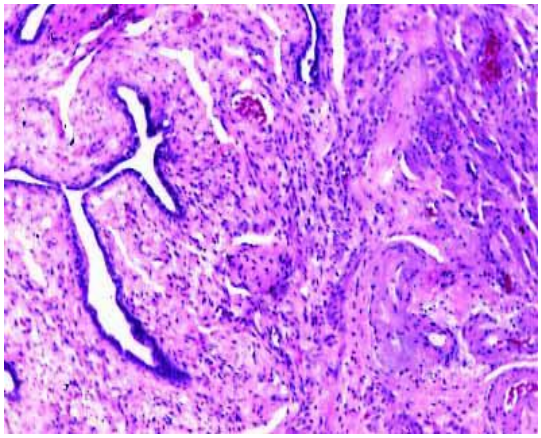


Figure:5a shows benign serous cystadenoma

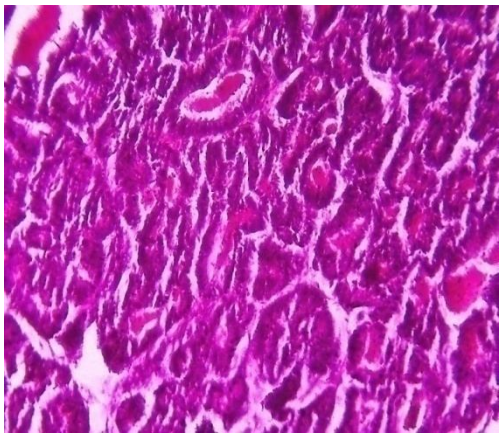


Figure 5 b : shows malignant serous cystadenocarcinoma

MUCINOUS TUMOUR

INCIDENCE:

Mucinous tumour constitute **8-10%** of epithelial tumours. They are multiloculated cysts. It can grow to a larger size and is usually unilateral. In 5 % cases it is bilateral. Tumours are usually benign constitute to 80% and malignancy in 5-10% cases.Thesetumours are usually associated with Brenner and dermoid cyst. Bilateral tumours often arises from metastasis from either mucocele of appendix and primary adenocarcinoma of appendix.

MORPHOLOGY:

Tumours are often multilocular, they have glistening surfaces. Cut section shows multiloculi, rich in mucin and have honey combed appearance.

Figure 6 a&b :gross appearance and cut section of mucinous tumour

HISTOLOGY:

Mucinous cyst is lined by tall columnar epithelium, with vacuolated cells with apical mucin. Lining epithelium is endocervical type.

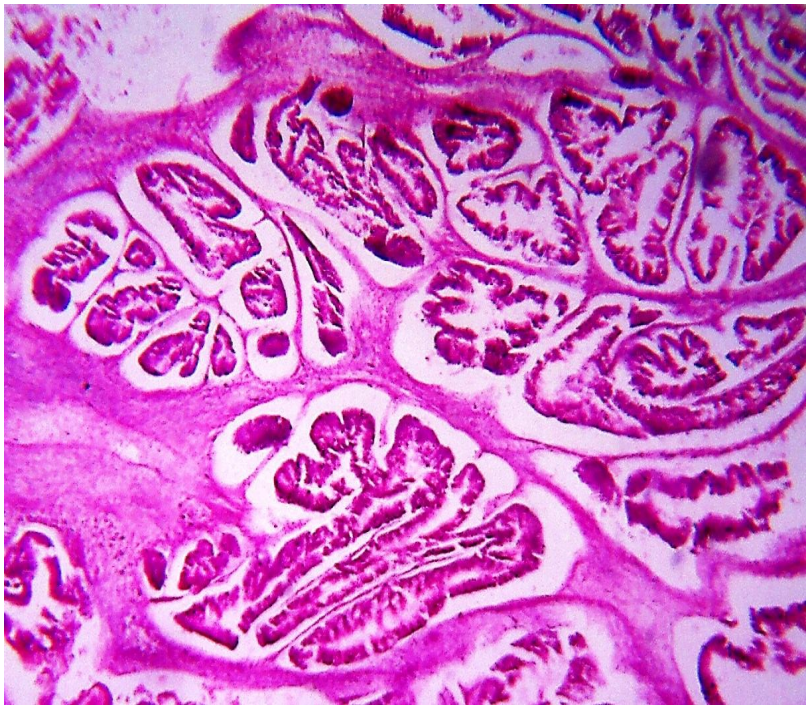


Figure 6c: shows histology of mucinous tumour

ENDOMETRIOD TUMOUR

INCIDENCE:

These tumours are mostly malignant, it accounts for 20% of all ovarian cancers, and 8-10% of epithelial ovarian tumours. It coexists in 15 % of cases with ovarian endometriosis.They are associated with endometrial carcinoma in 20% of cases.

MORPHOLOGY:

Tumours are solid, with cystic areas in between, often filled with haemorrhagic fluid.

HISTOLOGY:

They are lined by glandular epithelium resembles endometrium.

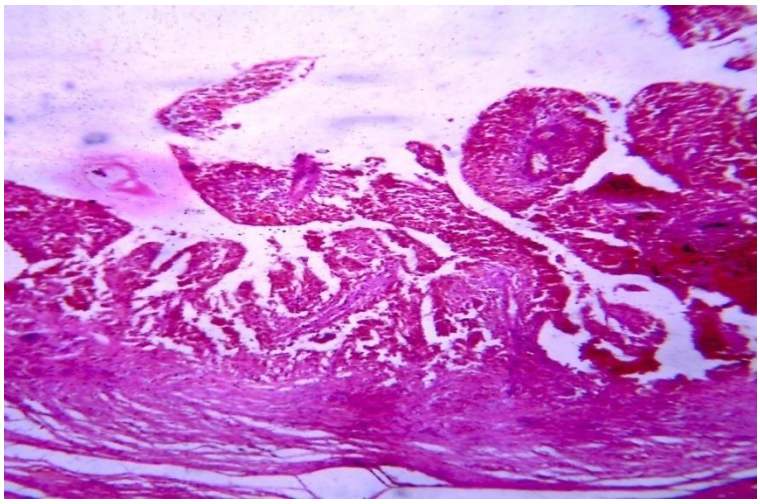


Figure7: Shows histology of endometriod tumour

CLEAR CELL TUMOUR

INCIDENCE:

About 5% of epithelial ovarian tumours are clear cell tumours.

MORPHOLOGY:

Tumor is highly malignant. Otherwise called mesonephroid tumour.

HISTOLOGY:

Histological types are Solid, Tubulocystic, Reticular and Papillary. The tumour contains clear cells that project the nuclei into apical cytoplasm with hobnail appearance. Focal areas of endometriosis is common.

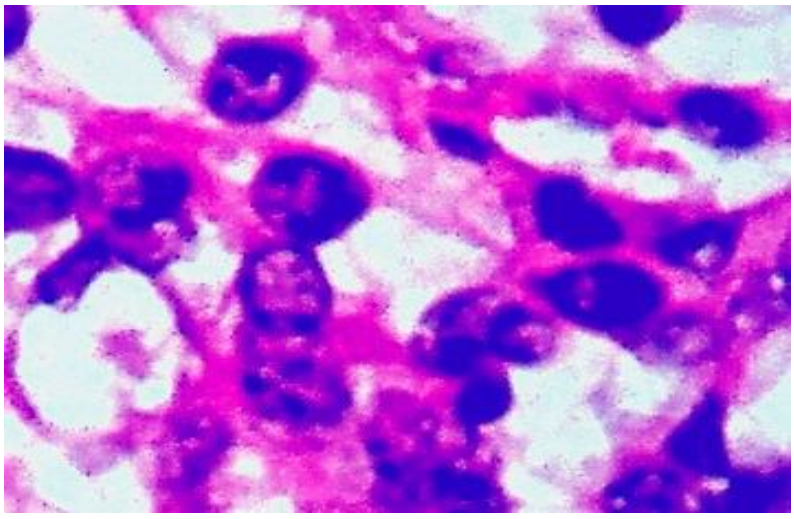


Figure 8:shows histology of clear cell carcinoma with hobnail cells

BRENNER TUMOUR

INCIDENCE:

It is a fibro-epithelial solid tumour constituting about 1-2% of total ovarian tumour. It may be associated with ascitis and hydrothorax called pseudomeig's syndrome. Rarely it becomes malignant. It occurs in postmenopausal women. This tumour is mostly unilateral, mostly benign. They have no endocrine function.

Hookup:

It resembles fibroma of the ovary. Cut surface shows gritty and yellowish grey colour.

HISTOLOGY:

The tumour shows background of fibrous tissue with nests of transitional epithelium (walthard cell nests) interspersed within it. These cells may demonstrate a longitudinal groove which resembles puffed wheat appearance. Nucleus resemble coffee bean appearance so called coffee bean nucleus.

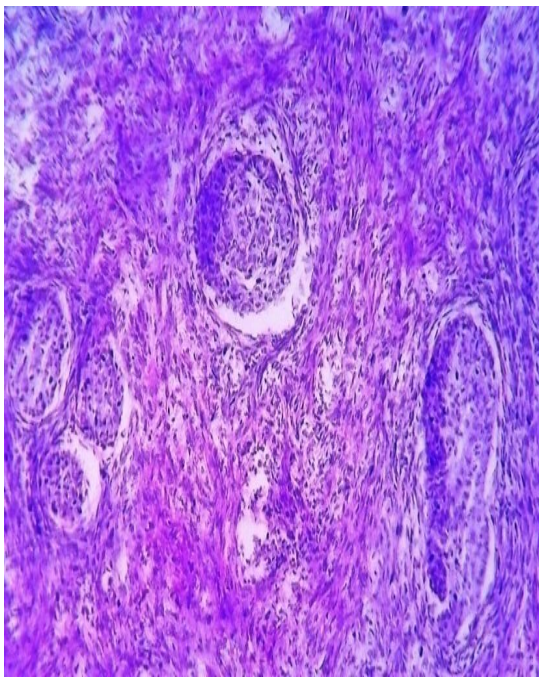


Figure 9a :histology of Brenner tumour with walthard cell nests

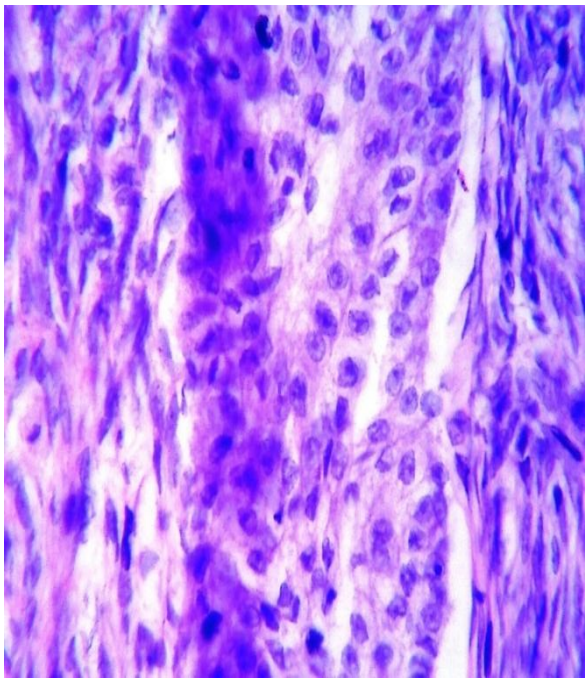


Figure 9 b :histology of Brenner which shows grooves

GERM CELL TUMOURS

Germ cell tumours contribute for **15-20%**of all ovarian tumours

Histologic Typing of Ovarian Germ Cell Tumors

1. Primitive germ cell tumor

- Dysgerminoma tumors
- Yolk sac tumor
- Embryonal carcinoma
- Polyembryoma
- Non-gestational choriocarcinoma
- Mixed germ cell tumor

2. Biphasic or Triphasic teratoma

- Immature teratoma
- Mature teratoma

❖ Solid

❖ Cystic

- ✓ Dermoid cyst
- ✓ Fetiform teratoma

3.Monodermal teratoma

- Thyroidtumour [Strumaovarii]]
  - Benign
  - Malignant
- Carcinoid
- Neuroendocrinetumour
- Carcinoma
- Melanocytic
- Sarcoma
- Sebaceoustumour
- Pituitarytumour

INCIDENCE OF GERM CELL TUMOUR:

95.5% of tumours shows benign cystic teratoma,60% of germ cell tumours are below the age of 20 yrs ***(scully RE et al, 1998)***..They arise from totipotentcells capable of producing ectodermal,mesodermal,endodermal components.

DERMOID

Dermoid contribute to about 5-10% of all cystic tumoursDermoid cysts are bilateral in 12-15% cases.Simple cyst have maximum incidence at the age of 40-50 years.Combined tumours arise in patients between the ages of 20-30 years. Epidermoid carcinoma occur in 1.7% of dermoid cyst.

CYSTIC TUMOURS:

It is unilocular with smooth surface.It contains sebaceous material,hair,teeth,bone,cartilage,thyroid tissue and bronchial mucous membrane.Some times these sebaceous material collects together in the form of small balls,the inner surface is called a ‘focus’ or embryonic node from which the hair project.

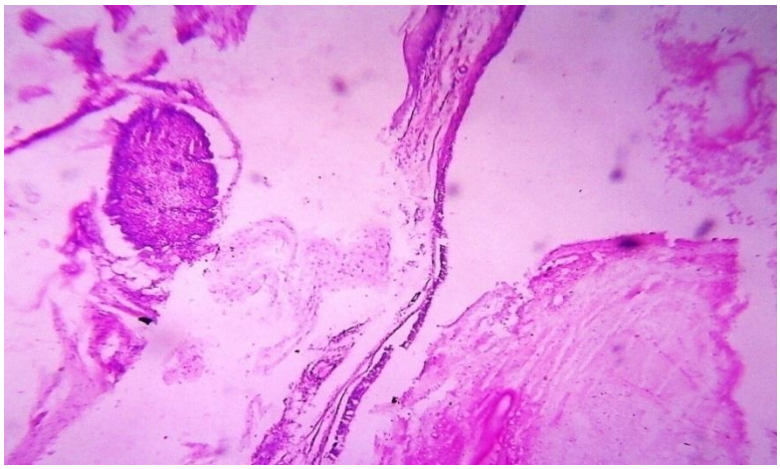


Figure 10 a :shows histology of dermoid cyst

SOLID TUMOURS:

They are mostly solid.Cut surface shows peculiar trabecular appearance. Solid part of tumour contains cartilage, bone, muscle, glia, piamater, intestinal mucous membrane, while hair and sebaceous material are found in cystic spaces. Extraovarian dermoid cyst arise from lumbar region, uterovesical area, parasacral region and rectovaginal septum.

DYSGERMINOMA

It corresponds to seminoma of testis.Itaccounts for 3-5% of all ovarian tumours. It usually occurs in young women with the average incidence of 20 years.Thetumour is solid with elastic rubbery consistency and with smooth, firm capsule.

The cut surface is yellow,with areas of degeneration and haemorrhage. It is often unilateral. It may be bilateral in 10% cases.This tumour is highly radiosensitive.The malignancy rate is 30-50%.

Figure 11 a:shows cut section of tumour with haemorrhage

HISTOLOGY

Lymphocytes and giant cells are found among the tumourcells.Lymphocytic infiltration of the fibrous septa along with large dark-staining nuclei with clear translucent cytoplasm are diagnostic features. The tumours are neutral and doesnot secrete hormones but secrete placental alkaline phosphatase,lactate dehydrogenase and BetaHCG.

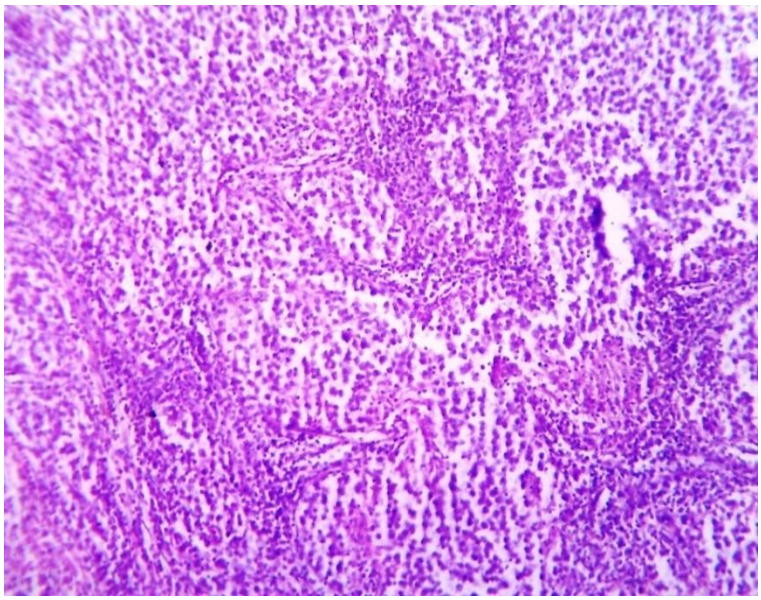


figure 11b : Histology of dysgerminoma with lymphocyte infiltrate with fibrous strands

YOLK SAC TUMOURS

Endodermal sinus tumour arise from primitive yolk sac.It is often unilateral.Most cells secrete AFP and alpha 1 antitrypsin.The tumouris sof t,greyish brown.The characteristic histologic feature is the presence of Schiller –Duval body.

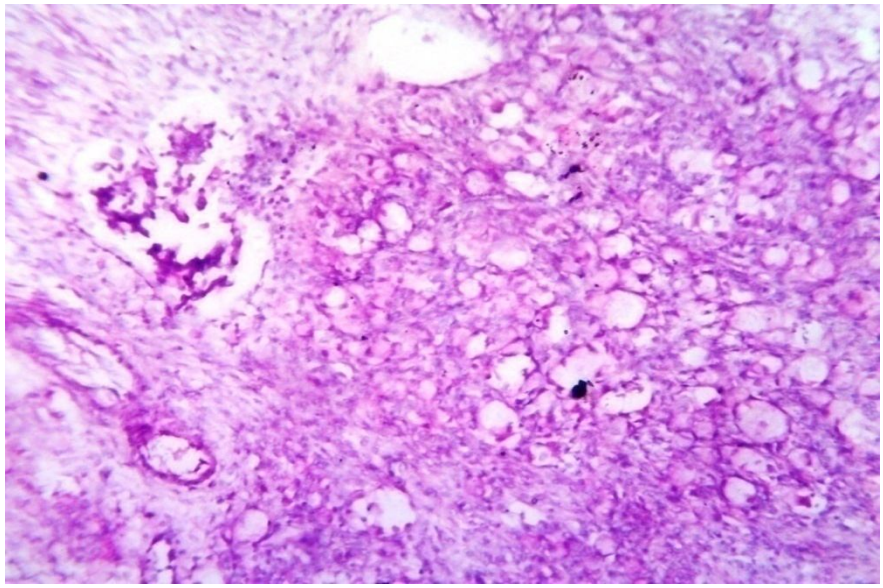


Figure 13 a: shows histology of yolk sac tumour

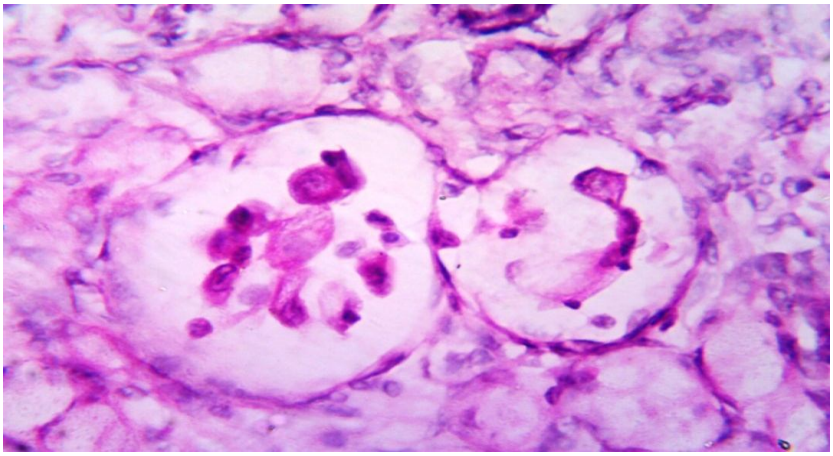


Figure 13 b: shows schiller duval body

SEX CORD STROMAL TUMOURS

FEMINIZING TUMOUR

↓

GRANULOSA CELL TUMOUR:

It contains cells that resembles granulosa cell of the graffian follicle.It constitutes 10% of malignant tumours.80% of women >40yrs while 5% of prepubertal girls. ***(Berek JS et al, 1995).*** It presents with precocious puberty in prepubertal girls with the development of secondary sexual characters.In adult life it presents with hyperestrogenic features.In postmenopausal women it presents with postmenopausal bleeding.

It is an oval shaped tumour with soft consistency.Cut surface is reticular or trabeculated with areas of internal haemorrhage. The outer surface is smooth and lobulated.

The cells are arranged either in cords or in trabeculae,surrounded by hyaline tissue.It contains **Call-exner bodies**.

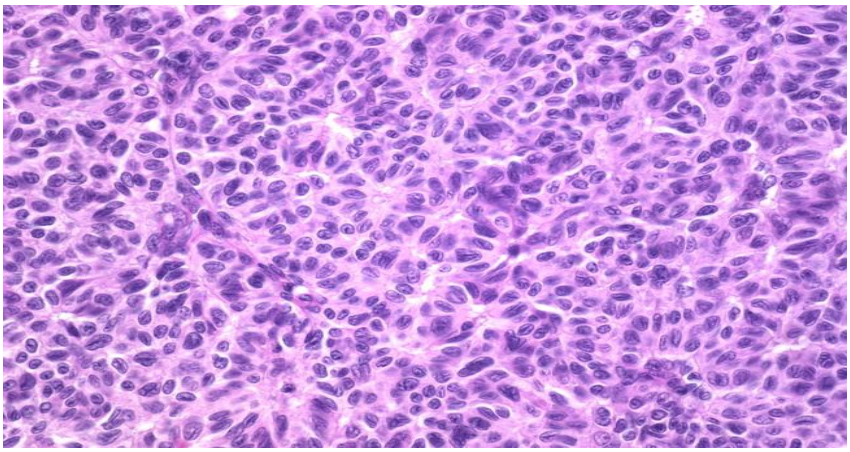
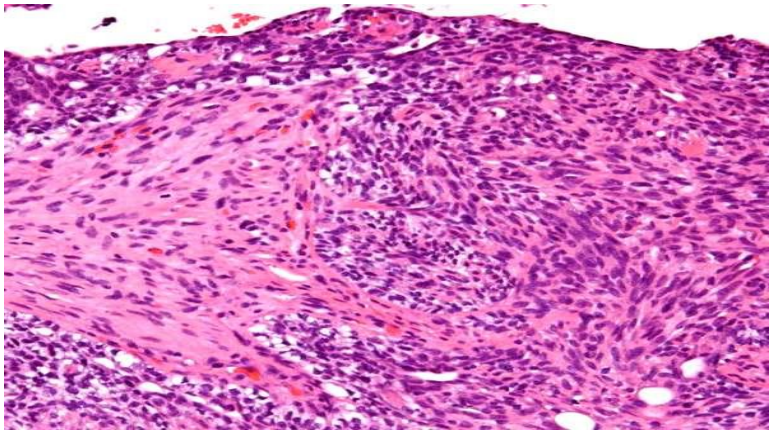


Figure 14:shows call exner bodies

THECA CELL TUMOUR:

This tumour is always unilateral. Cut surface is yellow in colour.The tumour consists of spindle shaped cells with luteinization of cells.**Figure 14 b:shows histology shows spindle cells with luteinization**



DIAGNOSIS

Ovarian tumour can be diagnosed from history,clinical examination and diagnostic modalities.History which include menstrual complaints,abdominal pain,other vague symptoms,any family history of malignancy and also any adnexal mass removal,marital and obstetric history. clinical examination include examination of supraclavicular nodes, palpation of Breast,presence of ascitis,adnexal mass evaluation by pervaginal and per rectal examination.

Diagnostic modalities to confirm ovarian tumours include:

- ULTRASONOGRAPHY
- CA125
- CT ABDOMEN AND PELVIS
- COLOUR DOPPLER ULTRASONOGRAPHY

ULTRASONOGRAPHY

IAN DONALD (Father of obstetric ultrasound) of University of Glasgow first used ultrasonography, for monitoring pregnancy . In the 1950's, he used ultrasonography to diagnose ovarian cyst . Three large studies concluded that transvaginal ultrasonography is the best modality for screening with 90% sensitivity for stage I disease with a PPV of 7.4–9.9%. [11]

Van Nagell et al.[48] screened 25,327 women using Transvaginal ultrasonography in asymptomatic women aged 50 years or over and women aged 25 years or over who had a family history of ovarian cancer.[4] They reported a sensitivity of 85% for all stages of disease with a specificity of 98.7% and a PPV of 14%. In addition, they reported that with annual Transvaginal screening they could able to detect the disease at stage I and stage II .

It identifies the site of origin of ovarian tumours,associated pathologies and ascites. It also aids in differentiating malignant and benign ovarian tumours.conventional ultrasonography is widely used in the diagnosis of ovarian masses by the morphological pattern of the tumors but it lacks specificity in distinguishing benign from malignant lesions.[28]

FEATURES OF BENIGN TUMOURS

- Cyst size <8 cm in premenopausal,<5 cm in postmenopausal women
- Thin wall
- smooth inner wall structure
- Anechogenicity of the lesions.

Figure 16 a.shows benign cystic tumour

FEATURES OF MALIGNANT TUMOURS

The sonographic finding of malignancy are

- Multilocularity
- Complex(solid/cystic)
- Bilaterality
- Thickness of cyst wall>3mm
- Septal thickness>2mm
- Papillary excrescences
- Ovarian volume>10cm^3
- Presence of solid materials
- Metastasis
- Presence of ascitis

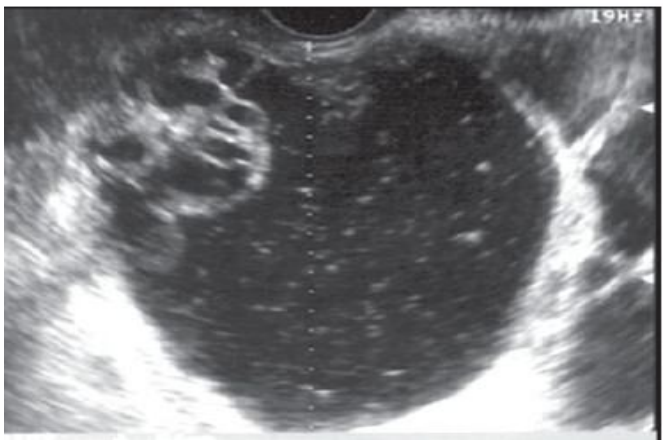


Figure 16 b. Shows **malignant cystic tumour with internal echoes**

Complex mass have indistinct inner wall structure and solid components. Solid tumours contains highly echogenic mass .They tend to be more often malignant(51.7%) .

If more than 80% has solid areas, they will be classified as solid and they carry risk of malignancy of 40% or more. Several researchers have distinguished the conditions, especially using pelvic ultrasound based on their morphological appearance like

(***Sassone et al., [40]1991; Lerner et*** al., 1994 [24]***; Valentin,*** 1999a ; 1999b [47]; ***Ferrazzi et al, 2005[11]***).

CT ABDOMEN AND PELVIS:

Computed tomography (CT) was introduced 30 years back into clinical practice . CT is widely used for the diagnosis of ovarian cancer for diagnosing the primary disease, for staging, monitoring response to treatment and diagnosis of recurrent disease.

Conventional CT scanners are made with a tube that generates a narrow x-ray beam that passes through the patient ,which is picked up by a row of detectors on the other side. The tube and detectors are positioned on the opposite sides of a ring and rotate around the patient. The incorporation of slip ring technology into the design of scanners in the late 1980s enables the tube to rotate in a single direction indefinitely (spiral or helical CT).

The time of scan is very much shorter. In many studies ,CT has a sensitivity of 59% to 63% and specificity of 81% to 83%.The false-negative predictive value is 37% to 41%, whereas the false-positive predictive value is 17% to 19%.

CT is superior to other modalities in diagnosing:

- Lobulated solid mass
- Lymph node metastases
- Involvement of the omentum
- Presence or absence of ascites
- Involvement of the liver

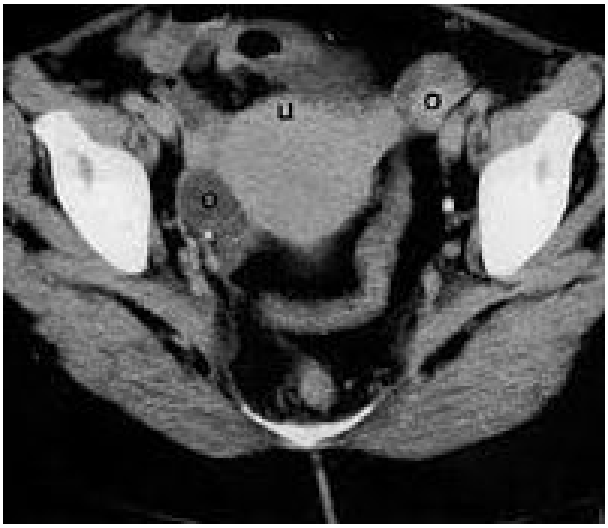


Figure 17.shows bilateral stage 1 b malignant tumour

The major disadvantage of CT scanners is the amount of radiation exposure to the patient. CT scan which involves a series of x-rays, which build up a three-dimensional picture of the inside of the body. It takes 10–30 minutes and it is painless. It has considerable amount of radiation hazard.

TUMOUR MARKERS

Tumour markers are substances that are identified in higher amounts in blood ,urine and body tissues of patients with specific malignancy.CA125 is a **Glycoprotein** used for screening and diagnosis of epithelial tumours of ovary. It is the antigenic determinant recognized by a monoclonal antibody of CA125 is a **mucin (**MUC 16) of more than 1M Da with an intracellular, trans membrane and extracellular domain.

The extracellular domain is heavily glycosylated and consists of multiple repeating subunits with 154 amino acids. A protease cleavage site is found in the extracellular domain. CA125 was first detected using the OC125 murine monoclonal antibody [2].

It is also used for monitoring of patients on chemotherapy and for follow up.It may also raised in other conditions like pelvic inflammatory disease ,endometriosis, peritonitis and in some malignant conditions like carcinoma breast,colon,lung and endometrium.Itmay be raised in 1% normal women.

values >***35U/L*** is significant

A number of factors are known to influence serum CA125 levels in healthywomen like age(premenopausal women have higher levels of CA125 than postmenopausal women),menstrual cycle(Some women have fluctuating serum CA125 levels throughout the menstrual cycle),pregnancy(CA125 increase during pregnancy),race(significantly higher CA125 are found in healthy causacian women compared to asian or african women).These factors should be taken into account when interpreting CA125 test results.

It is also used for follow up after surgery,when level increases it indicates residual tumour.CA125 increased in only 50% of stage1 ovarian tumour and 90% in stage 2 ovarian tumour.[22]Specificity of CA125 can be combined with transvaginal ultrasonography.Serum CA-125 is one of the most useful tumor markerin differentiating benign and malignant ovarian cancer.[2,21,22]However, the positive and negative predictive valuesof this marker are generally low[9,24]

COLOUR DOPPLER

Doppler was first described by **CHRISTIAN ANDREAS DOPPLER** in 1842 who described the Doppler Principle.

In 1955, Ultrasonic medical applications of this principle were applied by ***Shigeo Satomura and Yasuhara Nimura*** for observing blood flow.The technology used in this system relies on the fundamental piezo-electric crystal technology found by the ***Pierre Curie.***

The origin to the modern diagnostic ultrasound technique is based on the works of **Chilowsky and Langavin** SONAR (sound navigation and ranging) published in 1916, which was the first successful application of ultrasound.When ultrasound pulses are directed into a medium, it causes the particle in the medium to vibrate parallel to the direction of wave propagation, this process of transmitted vibration from particle to particle lead to propagation of ultrasound through medium.

Three possible interactions take place

- **Reflection:** Reflection occurs at the interface between two dissimilar medium. It is dependent on the tissues acoustic impedance and the beam's angle of incidence.

- **Refraction:** Binding of waves as they pass from one medium to another is called refraction can cause artifacts. Refraction artifacts cause spatial distortion and loss of resolution in the image.
- **Absorption:** Energy is dissipated, in the form of heat.

Ultrasound wave is generated by the piezoelectric crystals lead zirconate titanate in the transducer .As the sound pulse passes through the patient body it interact with tissue in accordance with the characteristics of targeted tissue. The results of these interactions are recorded for diagnosis in the form of ultrasound wave incident on a transducer.

The reflected waves are received by the transducer, these waves carry energy and they transmit the energy to the crystal elements. This compression forces the tiny dipole to change their orientation, which induces a voltage between the electrodes. The voltage is amplified and serves as the ultrasonic signal for display on an oscilloscope or television monitor.

The physical component of probe include, the **Handle** (the part held by operator), the **Shaft**(portion which enters the vagina),**Tip, head or footprint(**which houses the US crystal).most Transvaginal probes uses frequency in the range of 5 to 7.5 MHz. scan angle may vary from 90 to 115 degree scanning angles.

BIOLOGICAL EFFECT OF ULTRASOUND

Physical effects of ultrasound can be divided into two groups

1. Thermal
2. Non-thermal

THERMAL EFFECTS

Ultrasound produces heat through the attenuation of sound as it passes through tissues, which in turn causes loss of penetration and inability to image deeper tissues. Factors controlling tissue heating include

- Spatial focusing
- Frequency of ultrasound
- Duration of exposure
- Tissue type.

NON THERMAL EFFECTS

Non thermal mechanisms can result in application of radiation forces (non-ionizing) both at microscopic and macroscopic level resulting in exerted pressure and torque. Acoustic fields can also cause induced motion to flow of fluids known as streaming.

Acoustic cavitation is action of fields which generates bubbles which undergoes volume pulsation and collapse in response to acoustic field. Other results of this activity are free radicle generation, microstreaming around bubble and mechanical action from bubble collapse.

SAFTEY CONSIDERATIONS:

It seems overall thermal considerations do not adversely affect the safety in pulse echo scanning while for Doppler ultrasound the caution that needs to be exercised is that examination should be kept as short as possible.

Methods to minimize the harmful effects:

Effects can by minimized by

1. Setting machine on default output settings.
2. Keeping the time for which transducer is in contact to minimum.
3. Keep acoustic output at the minimum consistent with good results.

The general consensus as stated by **American institute of ultra sound in medicine** (AIUM) bio effects committee is that “no confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Where ever possible the principle of ALARA (as low as reasonably achievable) should be practiced.

DOPPLER PRINCIPLE

The sound waves whether perceived as low or high frequency will depend upon whether the sound source moving towards or away from the listener.the amount of this frequency shift is directly proportional to velocity of sound source.thus frequency shift between ultrasound transducer and echoes returning from Red blood cell are noted.

Blood flow velocity is directionaly proportional to blood pressure and is Inversely proportional to vascular resistance. sampling point on the line of the pulsed Doppler beamwas positioned where the colored dots within the tumor.This placement of the beam revealed the presence of vessels and these positions were followed and captured.

CONTINUOUS WAVE TRANSDUCER

Continuous transducer consists of a transmitter that continuously emits sound and a receiver continuously receives frequency shift. It doesnot discriminate echoes according to their depth.

PULSE WAVE TRANSDUCER

It emits ultrasound for a fraction of a second and then switch over to the receiver mode. This provide depth discrimination by echo delay time.

Echoes that are returning from specified tissue are measured.doppler gate or sample volume which are selected depth are positioned within the vessel lumen.Aquired signal fron specific anatomical location noted

An advanced variation of color Doppler is power Doppler and is found to have a better diagnostic potential than conventional Doppler [24]. Power Doppler measures the energy of a returning Doppler signal rather than analyzing the flow pattern. An advantage of power Doppler is that it can evaluate low-velocity blood flow. A further improvement of power Doppler is 3D power Doppler, providing imaging and measurement of blood flow in solid areas and excrescences of complex cysts [25]

Cohen et al. studied 71 women with solid and complex ovarian masses to evaluate if 3D power Doppler was superior to 2D power Doppler in evaluating ovarian masses. They found that all malignancies were correctly identified by both 2D and 3D imaging; however, the specificity significantly improved with the addition of 3D power Doppler . Availability of the instruments and the necessary expertise for interpretation has limited the use of both techniques.

Doppler waveforms (***Bourne et al.,[4] 1989; Hata et al.[17]***,1989; Kurjak et al 1991.,[23]Kurjak et al.,1993 [25])reports showed the superiority of this technique in screening ovarian cancer. (***Bourne et al., 1989; Kurjak etal.,*** 1991) reported the ability of the colour Doppler in differentiating benign from malignant tumors preoperative.

This was proposed by **Kurjak et al**(1993c). When no blood flow was detectable within the tumor,signal placed on peripheral areas of the tumour or theadnexal branch of the ovarian artery .Both pulsatility index (PI) and resistance index (RI)were calculated. The value of each artery was calculatedfrom a curve fitted to the average waveform over three cardiac cycles.

INTERPRETATION OF COLOUR DOPPLER

A colour Doppler system not only find frequency shift but also the direction of flow encoded by colour coding system

RED- Towards the transducer

BLUE- Away from the transducer

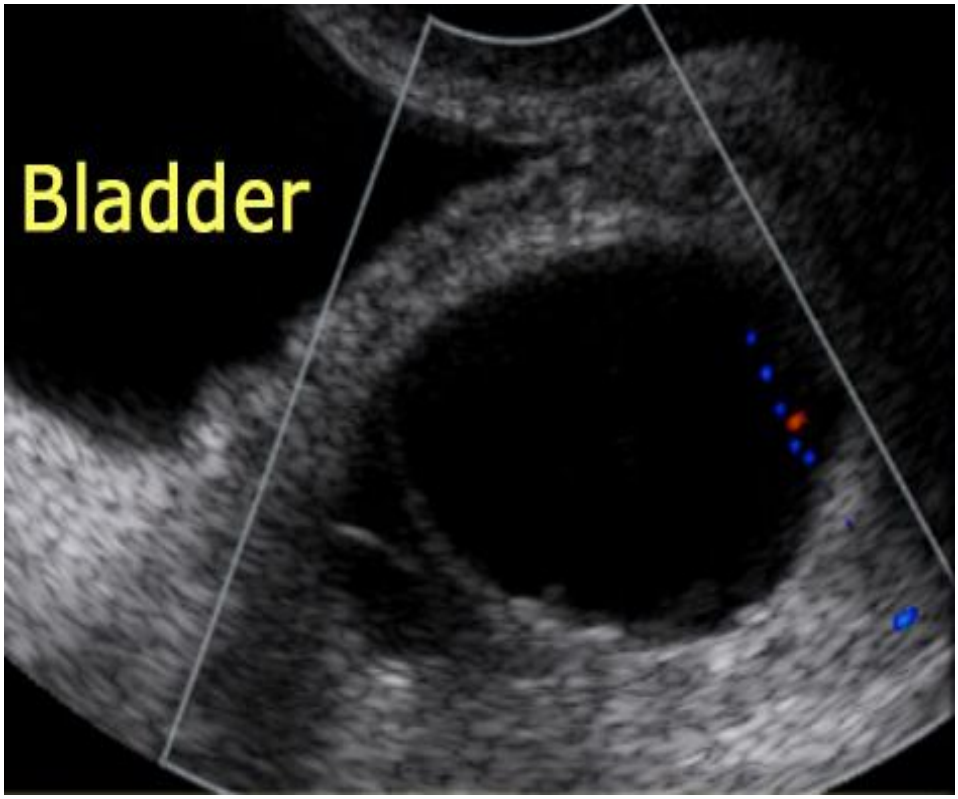


Figure 18 a.shows colour Doppler of benign tumour with less vascularity

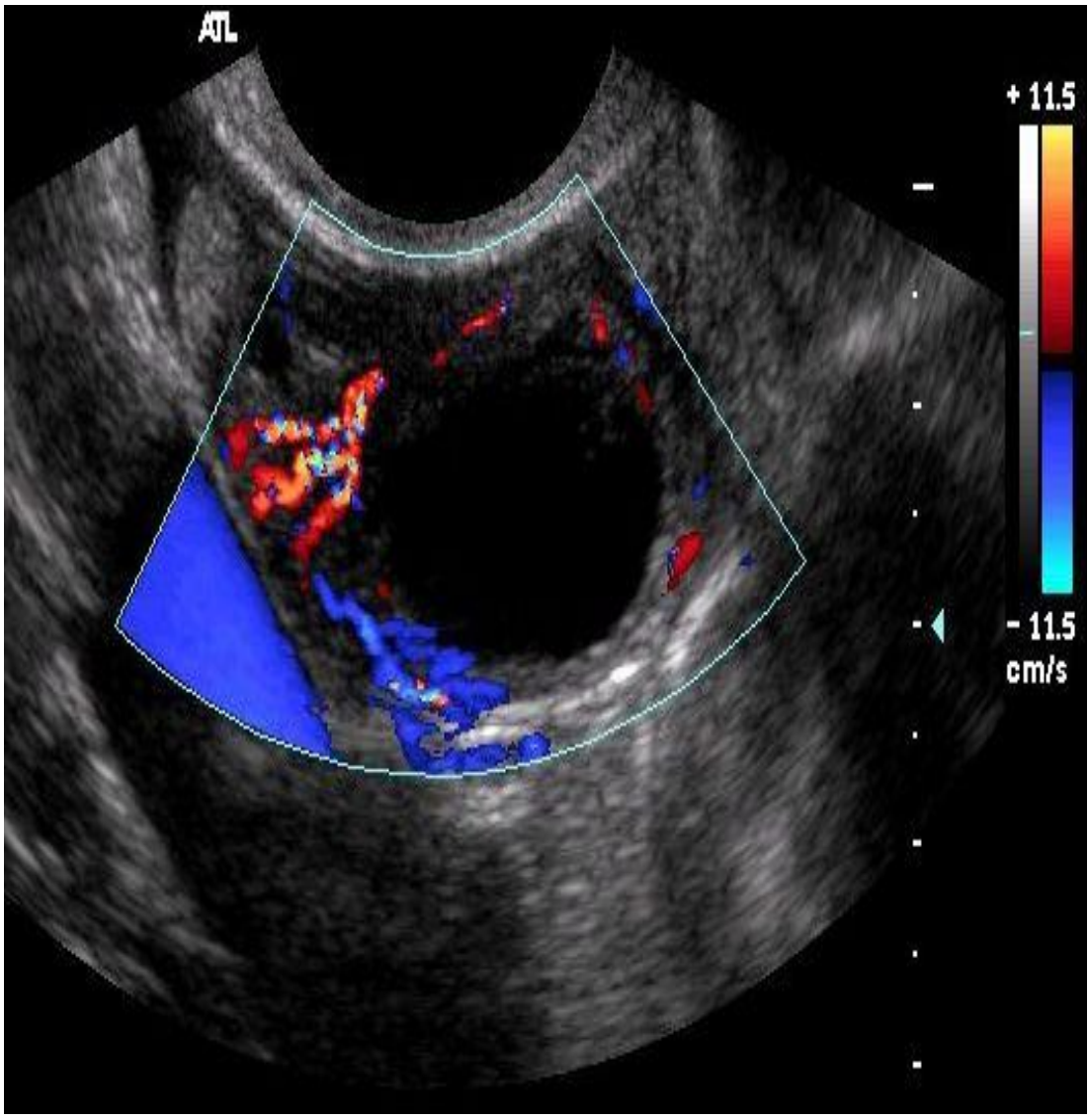


Figure 18 b .shows colour Doppler image of malignant tumour with increased flow

Several angle independent indices are noted to analyse frequency shift

1.S/D ratio of **STUART**

2.Formula used for calculating RI

Resistive index of **POURCELOT:**

RI = (S-D)/S

3.The formulas used for PI

PI-Pulsality index

PI = (S-D)/mean

S - Maximum Doppler frequency shift in Systole

D – Minimum Doppler frequency shift in Diastole

Signals from various areas within the tumor were determined but the lowest PI and RI were considered for data analysis.Furthermore, the area distribution of visualized vesselsin the adnexal masses was also categorized and recorded as in the center of the mass, in the septum, in the papillae, at peri-tumour areas.

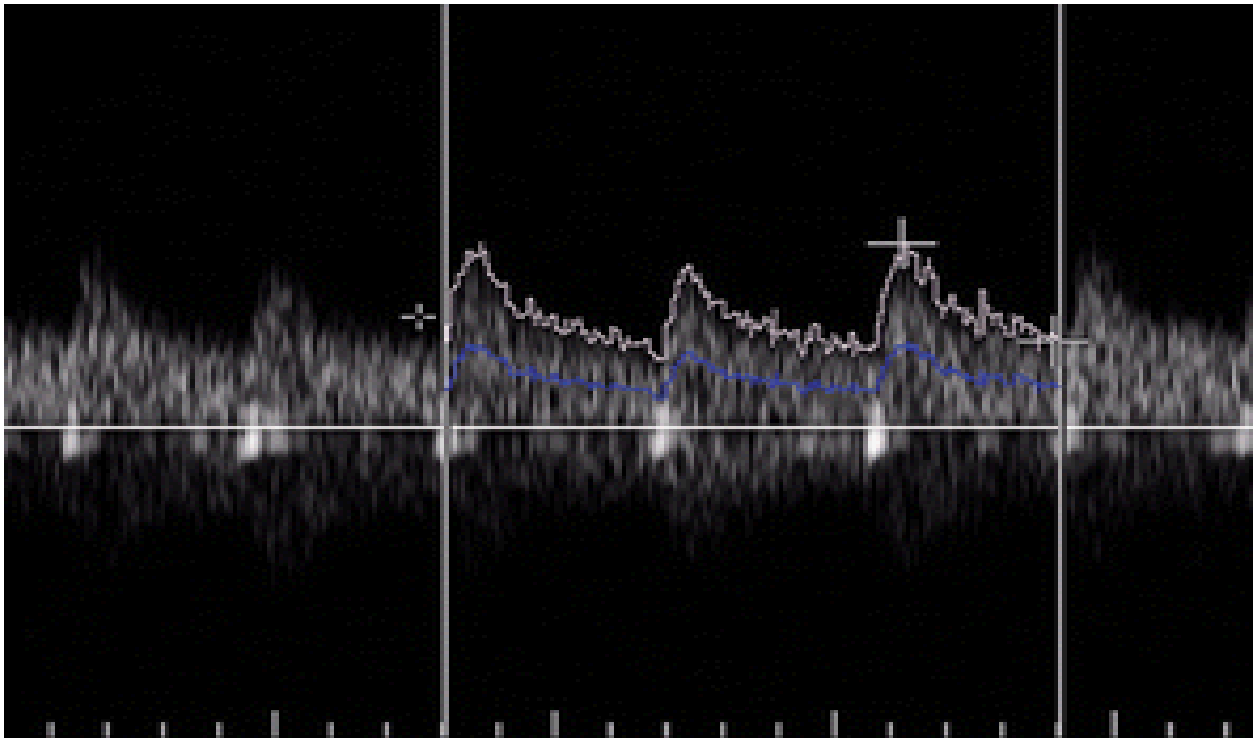


figure 18 c.shows Doppler waveforms of ovarian vessels.

Malignant neoplasm offer low resistance to blood flow due to presence of aberrant tumour vessels.

RESISTIVE INDEX

Cutoff values

BENIGN	>0.4
MALIGNANT	<0.4

Table no 1a:cut off values of RI

Cutoff values used by most of researches for RI

STUDY	CUT OFF VALUE
Kurjak et al	0.4
Timor-tritsch et al	0.4
Zanetta et al	0.56

Table 1b:cut values of RI in other studies

In previous studies, some authors suggested the existence of clear cut-off points of PI and RI of benign and malignant tumours. ***Kurjak et al (1991)*** [25] reported only one false positive and two false negative results in study population of 624 benign ovarian tumors and 56 malignant tumors by using a cut-off value of RI-0.4.

Timor-Tritsch et al (1993) [45] explained that RI value of 0.4 had sensitivity 93.8% and specificity of 98.7% which was different from the studyof ***Zanetta et al(1994).***[51] Who used the cut off value of RI as 0.56.

PULSALITY INDEX

Cutoff values

BENIGN	>1
MALIGNANT	<1

Table 2a:cutoff value of PI

STUDY	CUTOFF VALUES
Sengoku et al	1.5
Theeratongsong	1.2
Weiner et al	1.0

Table 2b: cut off values of PI in other studies

Sengoku et al (1994) [42]concluded sensitivity and specificity of 81.3% and 91.7% respectively when the cutoff value of PI 1.5. Study done by ***Theera tong song*** [46] reported that, among 306 patients 191 are benign and 115 aremalignant.sensitivity and specificity of RI is 93% and 92.7%respectively.sensitivity and specificity of PI is 94.8% and 93.2%respectively.

Among 306 cases, the mean PI values of tumour arteries were 1.73 , 0.97 and 0.88 for benign tumor, low malignant potential tumor and cancer, respectively. When cancer and low malignant potential tumors are considered together, their mean PI was 0.89. The mean PI in the benign and malignant group was significantly different (**Student's T test, p<0.001).**

Based on **receiver-operating characteristics** (ROC) curve area best cut-off Value PI was 1.20, which gave sensitivity and specificity of 93.0% and92.7%, respectively ,with area under curve of **0.960** with 95%Confidence interval. The mean RI values were 0.81 , 0.50 and 0.44 for benign tumor, low malignant potential tumor and cancer, respectively. The mean RI was 0.45 if malignant and Borderline tumors were considered together. The mean RI in the benign and malignant group was significantly different(Student's Ttest, p<0.001). Based on receiver-operating characteristics(ROC) curve with area under curve of **0.95** with (95% Confidence interval), the best cut-off RI was 0.62, which gave sensitivity and specificity of 94.8% and 93.2%, respectively

AIMS AND OBJECTIVE OF THE STUDY

- To study the accuracy, sensitivity and specificity of Colour Doppler in diagnosing Benign and Malignant ovarian tumours in 15-60 yrs age group patients attending Gynaecology Clinic at Government Kilpauk Medical College Hospital, Chennai.
- To study the incidence of age group in which the malignancy is most common.

INCLUSION CRITERIA

- All women diagnosed to have significant adnexal mass (size > 5 cm) between 15 to 60 years.

EXCLUSION CRITERIA

- Known case of ovarian tumour came for second look surgery
- Anechoic unilocular cyst <5 cm in ovary that resolves on follow up
- Endometriotic cyst which likely to give false positive results.

MATERIALS AND METHODS

Ethical Committee

Ethical committee clearance obtained in January 2012.

Study Design

Prospective observational study

Place of Study

Gynaecology Outpatient Department at Kilpauk Medical College,Chennai.

Duration of study-January 2012 –September 2013

Sample size-75 calculated by the formula

Sample Size for Frequency in a Population

Population size(for finite population correction factor or fpc)(*N*):	250
Hypothesized % frequency of outcome factor in the population (*p*):	7%+/-5
Confidence limits as % of 100(absolute +/- %)(*d*):	5%
Design effect (for cluster surveys-*DEFF*):	1

Sample Size(*n*) for Various Confidence Levels

Confidence Level(%)	**Sample Size**
95%	72

Equation

Sample size $n = [DEFF*Np(1-p)]/ [(d^2/Z^2_{1-\alpha/2}*(N-1)+p*(1-p)]$

METHODS OF COLLECTION OF DATA

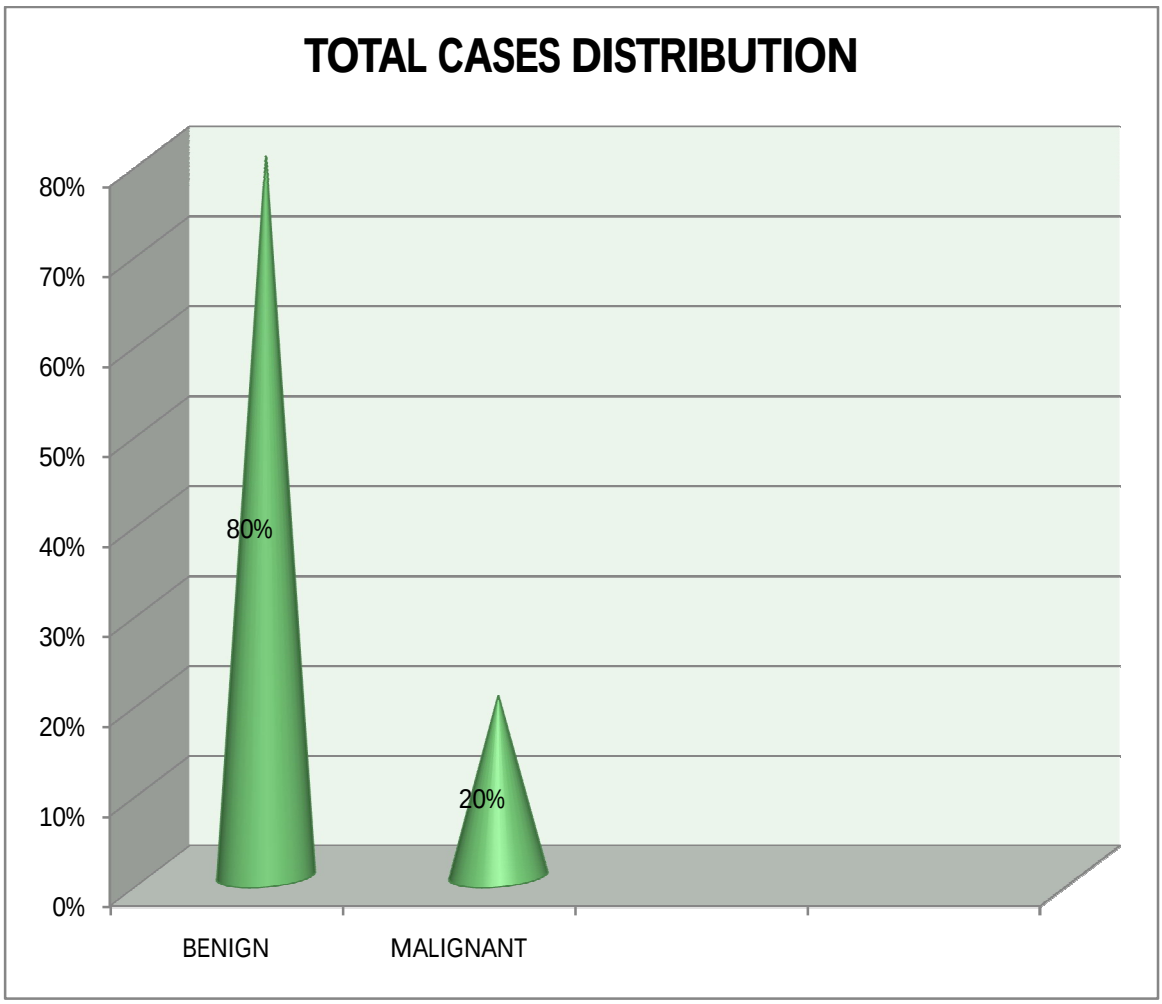
All ovarian tumour cases posted for surgery were selected and data obtained by complete history starting from presenting complaints, history of presenting illness, obstetric history, menstrual history, past history of adnexal mass removal, family history of malignancy, clinical examination including complete gynaecological examination done .

All routine investigations done with specific investigations like Ultrasonography, CT abdomen and pelvis,CA125 and Colour Doppler done calculating resistive and pulsality index. Findings are noted intraoperatively. Finally results were comparedwith Histopathology[HPE]

STATISTICAL ANALYSIS:

Chart:1

TOTAL INCIDENCE OF BENIGN AND MALIGNANT CASES AMONG 75 SAMPLE SIZE



This chart shows the distribution of benign and malignant tumours

CORRELATION OF AGE WISE DISTRIBUTION AND HPE

TABLE NO:3.1

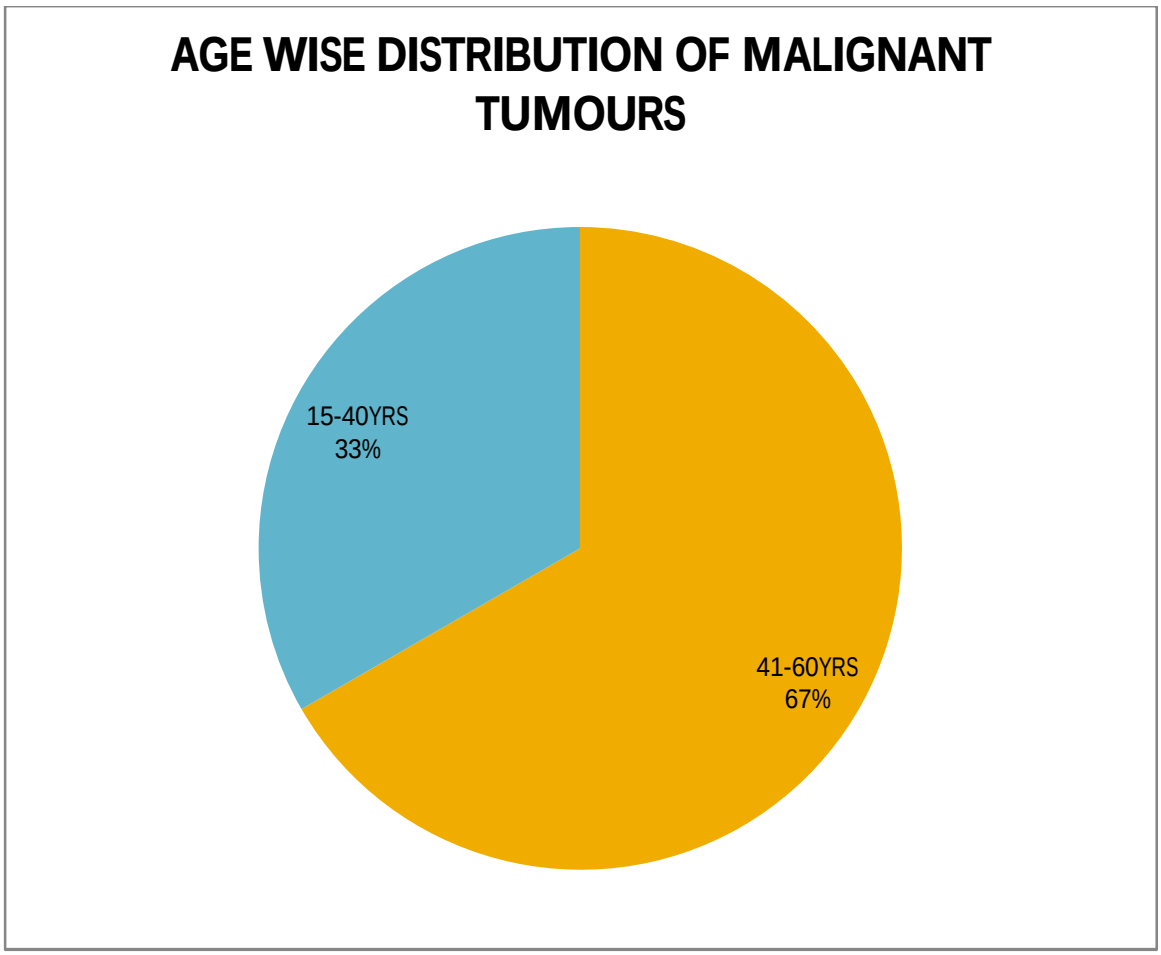
			HPE		
			BENIGN	MALIGNANT	Total
AGE GROUP	15-40yrs	Count	36	5	41
		% within HPE	60.0%	33.3%	54.7%
		% of Total	48.0%	6.7%	54.7%
	41-60yrs	Count	24	10	34
		% within HPE	40.0%	66.7%	45.3%
		% of Total	32.0%	13.3%	45.3%
	Total	Count	60	15	75
		% within HPE	100.0%	100.0%	100.0%
		% of Total	80.0%	20.0%	100.0%

Table:3.2

pearson chi square value	3.443
P value(Asymp.sig.2-sided)	0.064

Computed by 2*2 table.significant at <0.05

Pie Chart: 1

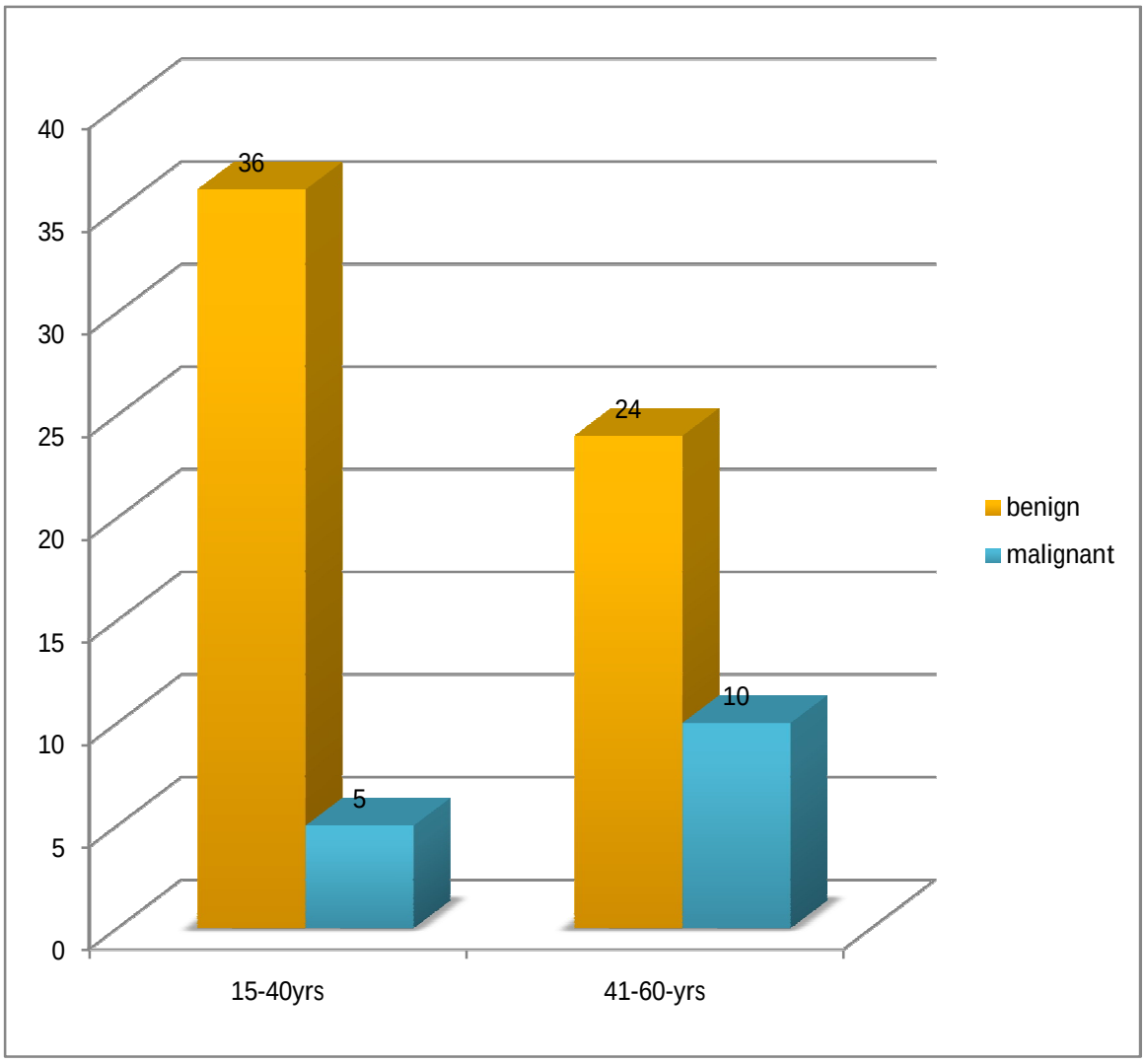


33% is malignant in age group **15-40yrs**,whereas **67%** is malignant in **41-60yrs** age group.

From the above data, It is found that malignancy is most common in the age group of **41-60yrs.**

From table no 3.2 ,**p value -0.064**,which is statistically not significant.

BAR CHART :1



Barchart showing Distribution of age groups in benign and malignant tumour

CORRELATION OF MENOPAUSAL AGE WITH HPE

Table :4.1cross table

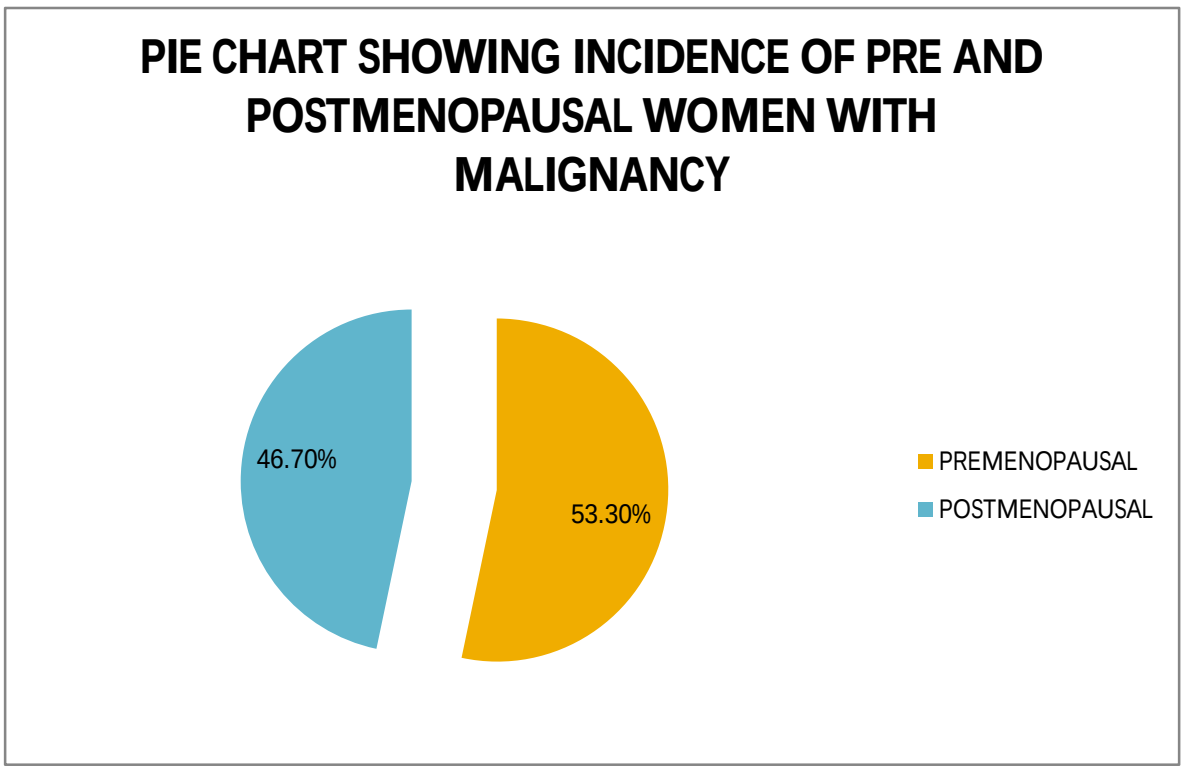
		HPE		
		BENIGN	MALIGNANT	Total
PRE MENOPAUSAL AGE	Count	49	8	57
	% within HPE	81.7%	53.3%	76.0%
	% of Total	65.3%	10.7%	76.0%
POST MENOPAUSAL AGE	Count	11	7	18
	% within HPE	18.3%	46.7%	24.0%
	% of Total	14.7%	9.3%	24.0%
Total	Count	60	15	75
	% within HPE	100.0%	100.0%	100.0%
	% of Total	80.0%	20.0%	100.0%

Table:4.2

Pearson chi square value	5.281
Asym sig.(2-sided)	0.022
Kappa value	0.464

Computed by 2*2 table.significant at <0.05

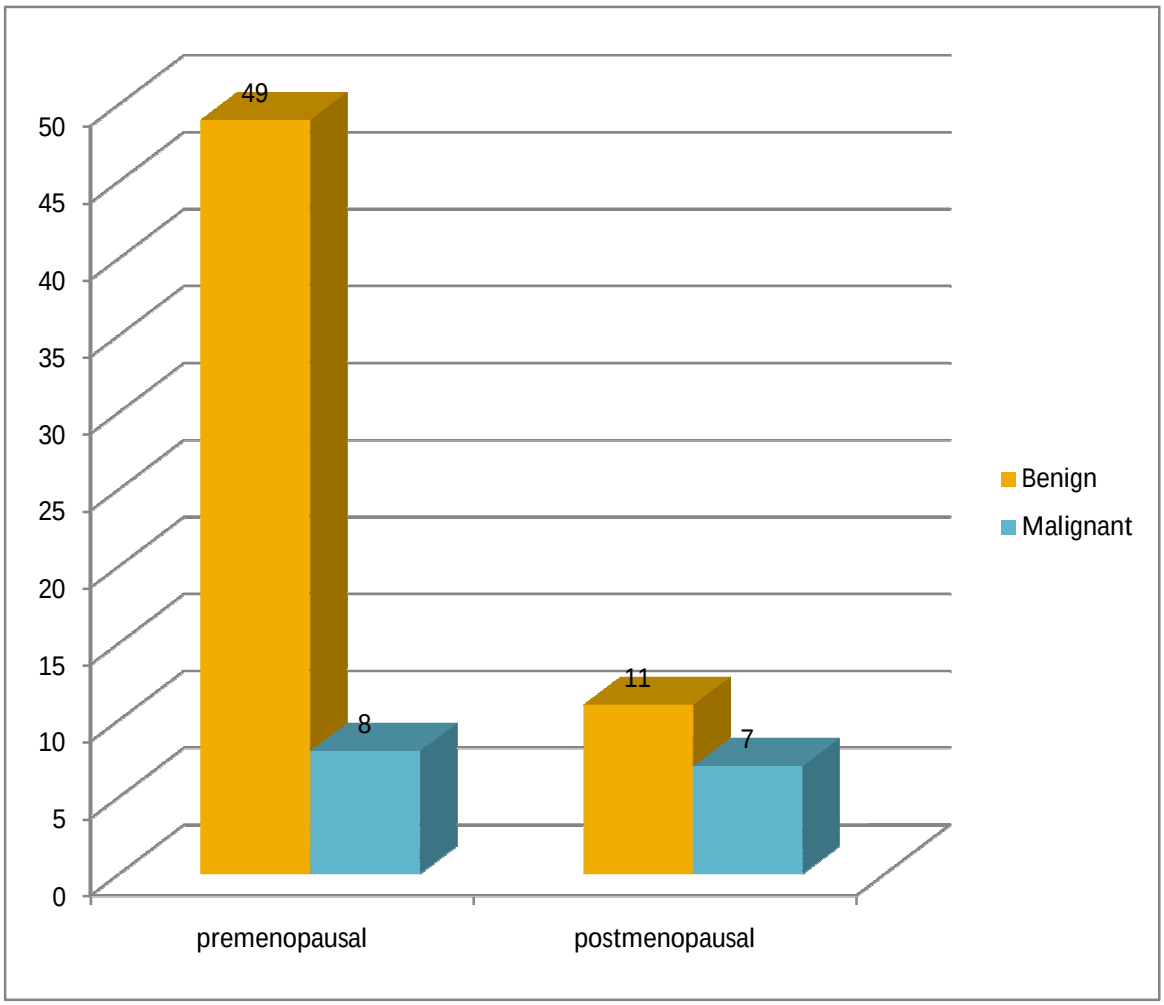
PIECHART 2



From table no:4.1

It is clear that among malignancy 8(**53.3%)** are premenopausal and 7 (**46.7%)**are postmenopausal.P value -0.022,which is statistically not significant.Kappa value -0.464, which has moderate significance.

BAR CHART:2



Bar Chart showing association of postmenopausal age with malignancy

CORRELATION OF HISTORY OF MALIGNANCY WITH HISTOPATHOLOGY

Table :5.1 Cross tab

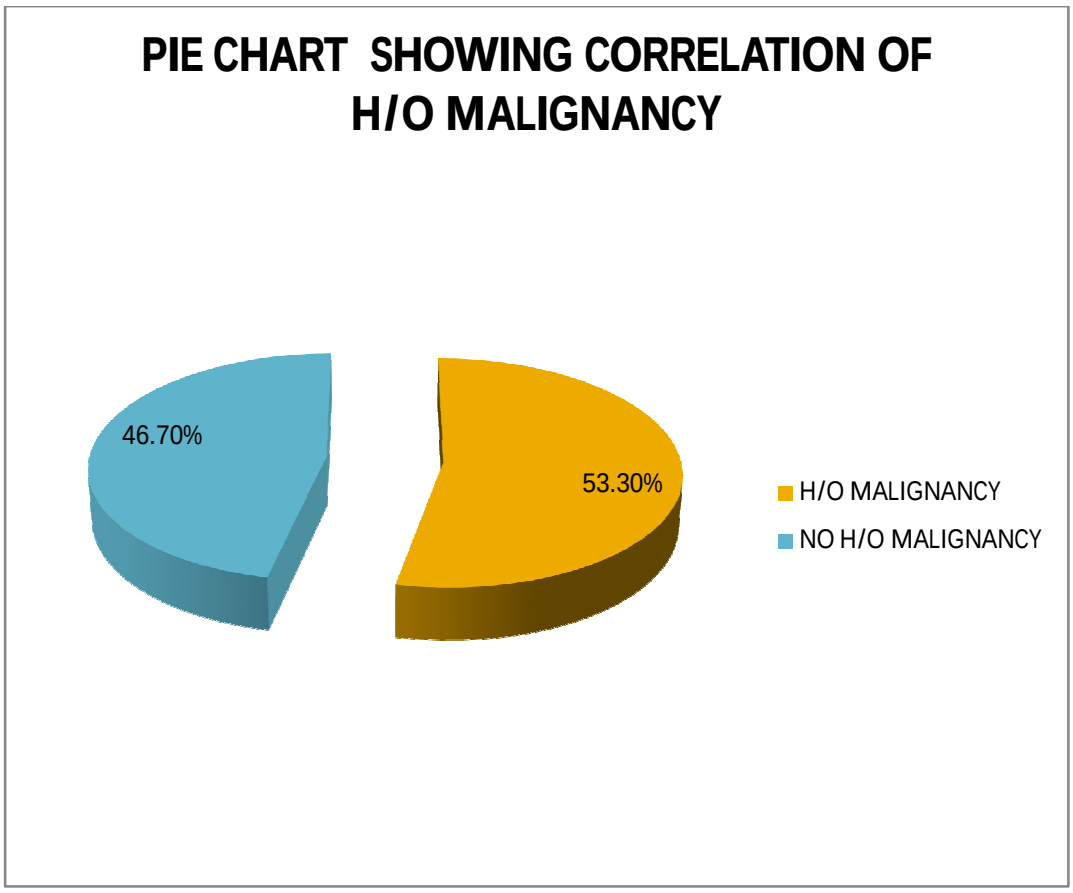
			HPE		
			Benign	Malignant	Total
	No H/O Malignancy	Count	60	7	67
		% within HPE	100%	46.6%	89.3%
		% of Total	80.0%	9.3%	89.3%
	H/o Malignancy	Count	0	8	8
		% within HPE	0%	53.3%	10.7%
		% of Total	0%	10.7%	10.7%
	Total	Count	60	15	75
		% within HPE	100.0%	100.0%	100.0%
		% of Total	80.0%	20.0%	100.0%

Table :5.2

Pearson chi square value	5.222
P value (2 sided sig)	0.024

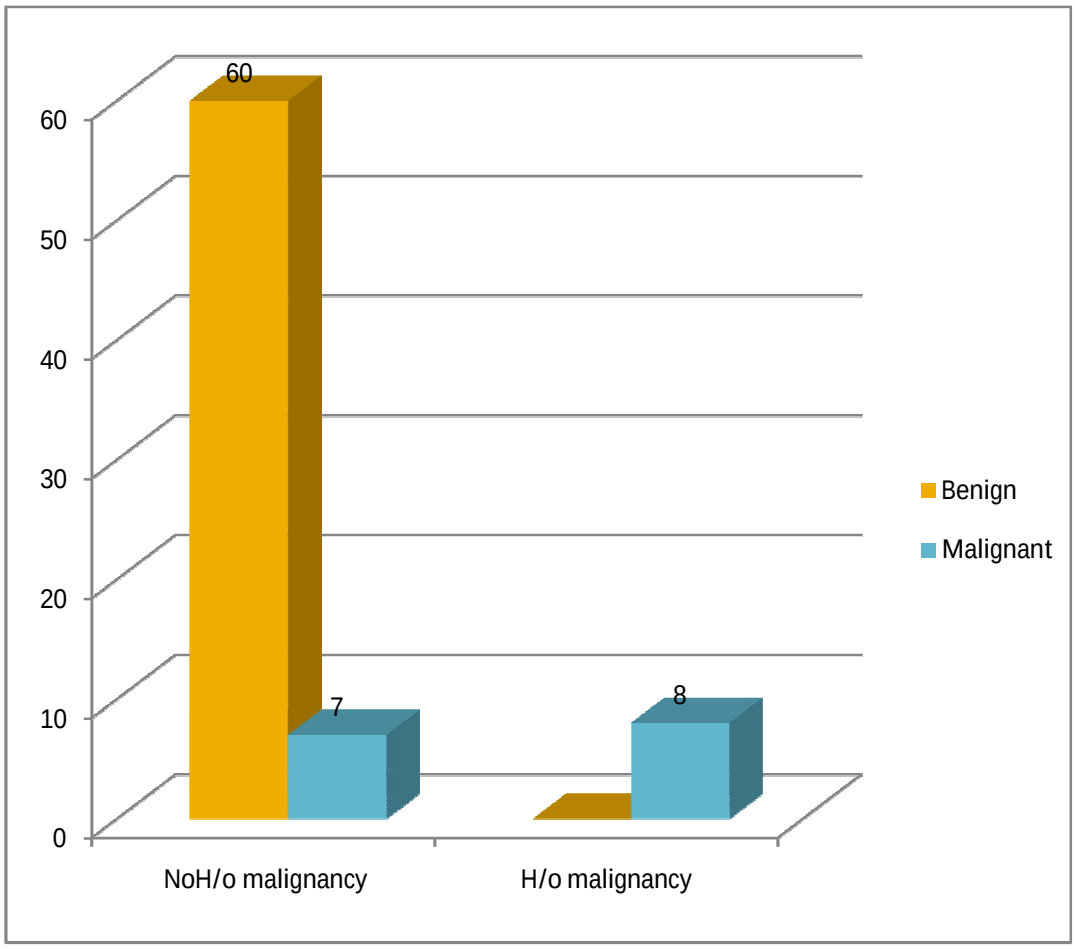
Computed by 2*2 table.significant at <0.05

Pie Chart:3



From table no:5,it is noted that **8** among **15** malignant patients have history of malignancy constituting about **53.3% .**

BAR CHART:3



Barchart showing association of H/o Malignancy with malignant tumours

CORRELATION RESULTS OF ULTRASOUND WITH HISTOPATHOLOGY

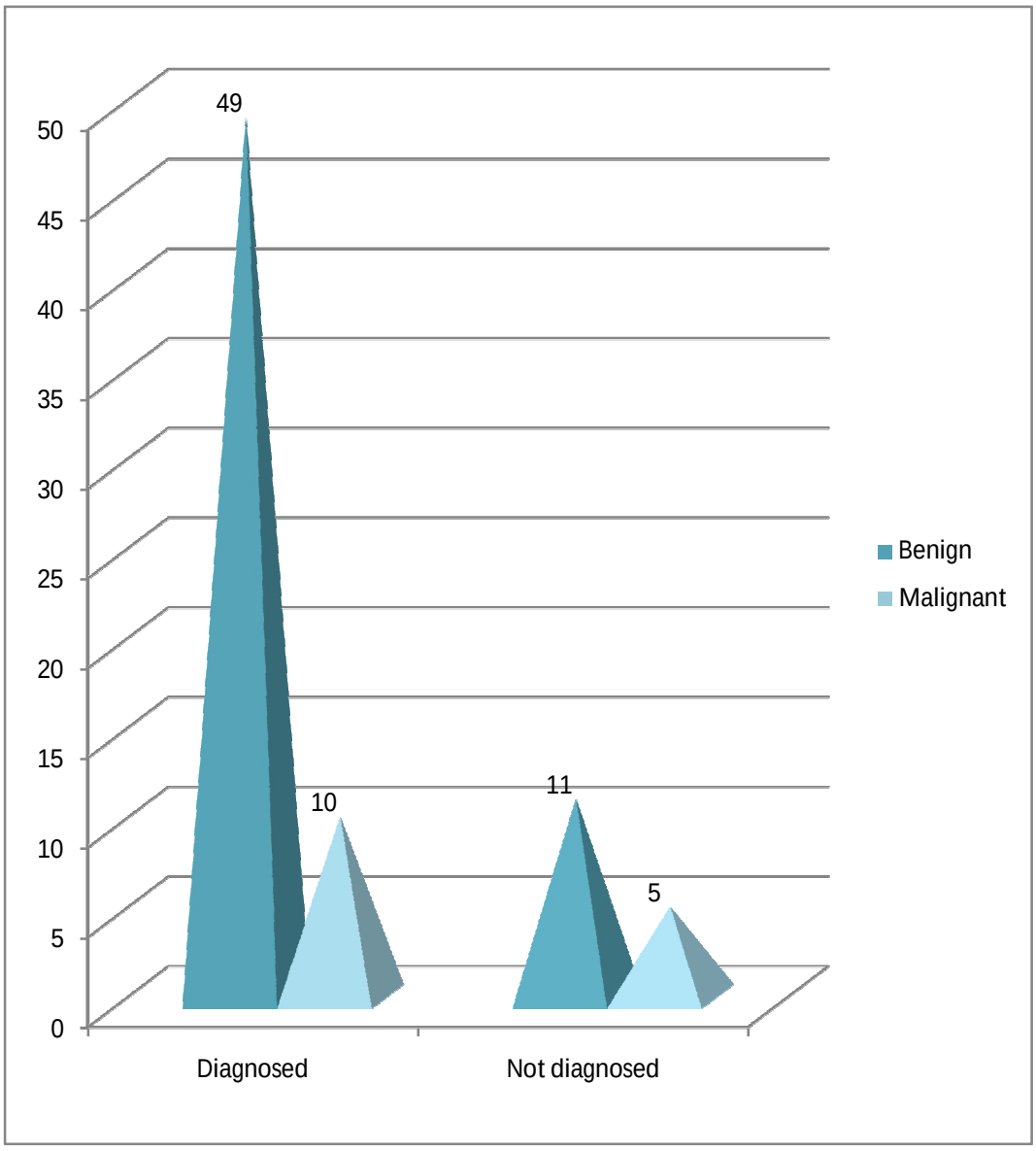
Table:6.1 Crosstab

			HPE		
			Benign	Malignant	Total
USG	Benign	Count	49	5	54
		% within HPE	81.7%	33.3%	72.0%
		% of Total	65.3%	6.7%	72.0%
	Malignant	Count	11	10	21
		% within HPE	18.3%	66.7%	28.0%
		% of Total	14.7%	13.3%	28.0%
	Total	Count	60	15	75
		% within HPE	100.0%	100.0%	100.0%
		% of Total	80.0%	20.0%	100.0%

Kappa	**0.420**
App sig.	**.000**

Table :6.2

BAR CHART:5 **USG WITH HPE**



RESULTS OF ULTRASONOGRAPHY

Table:6.3

Sensitivity	**66.67%**
Specificity	**81.67%**
Positive likelihood value	**3.64**
Negative Likelihood Ratio	**0.41**
Disease prevalence	**20%**
Positive Predictive Value	**47.62%**
Negative Predictive Value	**90.74%**

Table 5: shows ultrasound results

Hence the sensitivity of ultrasonography is **66.7%** And specificity is **82%**.

Kappa is 0.420 which is statistically significant

CORRELATION OF CT ABDOMEN AND PELVIS RESULTS WITH HISTOPATHOLOGY

Table:7.1

Crosstab

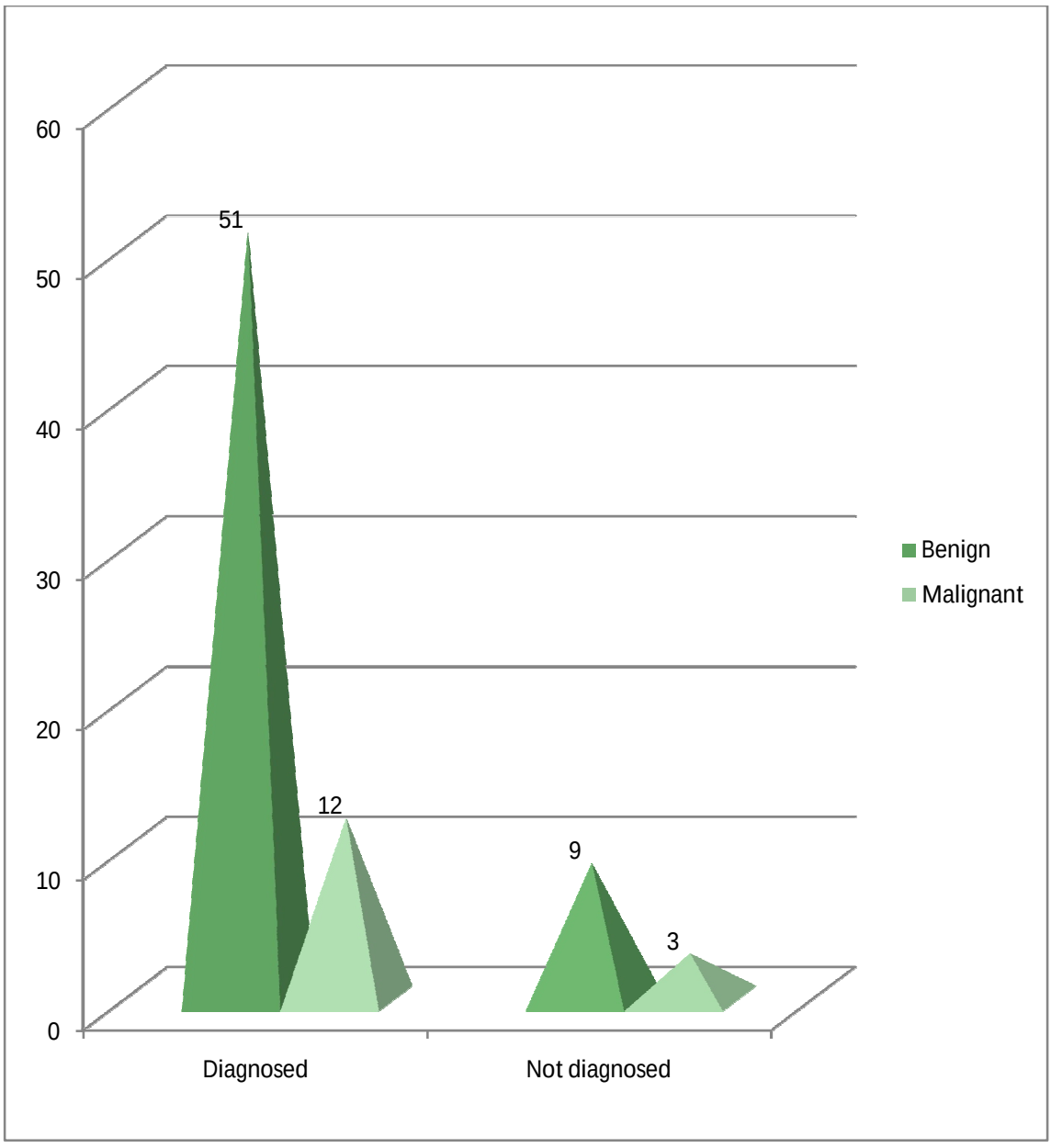
			HPE		
			0	1	Total
CT	0	Count	51	3	54
		% within HPE	85.0%	20.0%	72.0%
		% of Total	68.0%	4.0%	72.0%
	1	Count	9	12	21
		% within HPE	15.0%	80.0%	28.0%
		% of Total	12.0%	16.0%	28.0%
	Total	Count	60	15	75
		% within HPE	100.0%	100.0%	100.0%
		% of Total	80.0%	20.0%	100.0%

It diagnose **85%** of benign tumour and **80%** of malignant tumours.

Table:7.2

Kappa value	0.565
App.sig	0.000

BAR CHART:5



This bar chart correlate the CT with HPE

RESULTS OF CT ABDOMEN AND PELVIS

Table:7.3

Sensitivity	**80.00%**
Specificity	**85.00%**
Positive Likelihood Ratio	**5.33**
Negative Likelihood Ratio	**0.24**
Disease prevalence	**20.00%**
Positive Predictive Value	**57.14%**
Negative Predictive Value	**94.44%**

From the above study, it is noted that the sensitivity and specificity of ultrasonography is **80%** and **85%** respectively**.**kappa value –0.565 which has moderate significance.

CORRELATION OF CA125 RESULTS WITH HISTOPATHOLOGY

Table:8.1

Crosstab

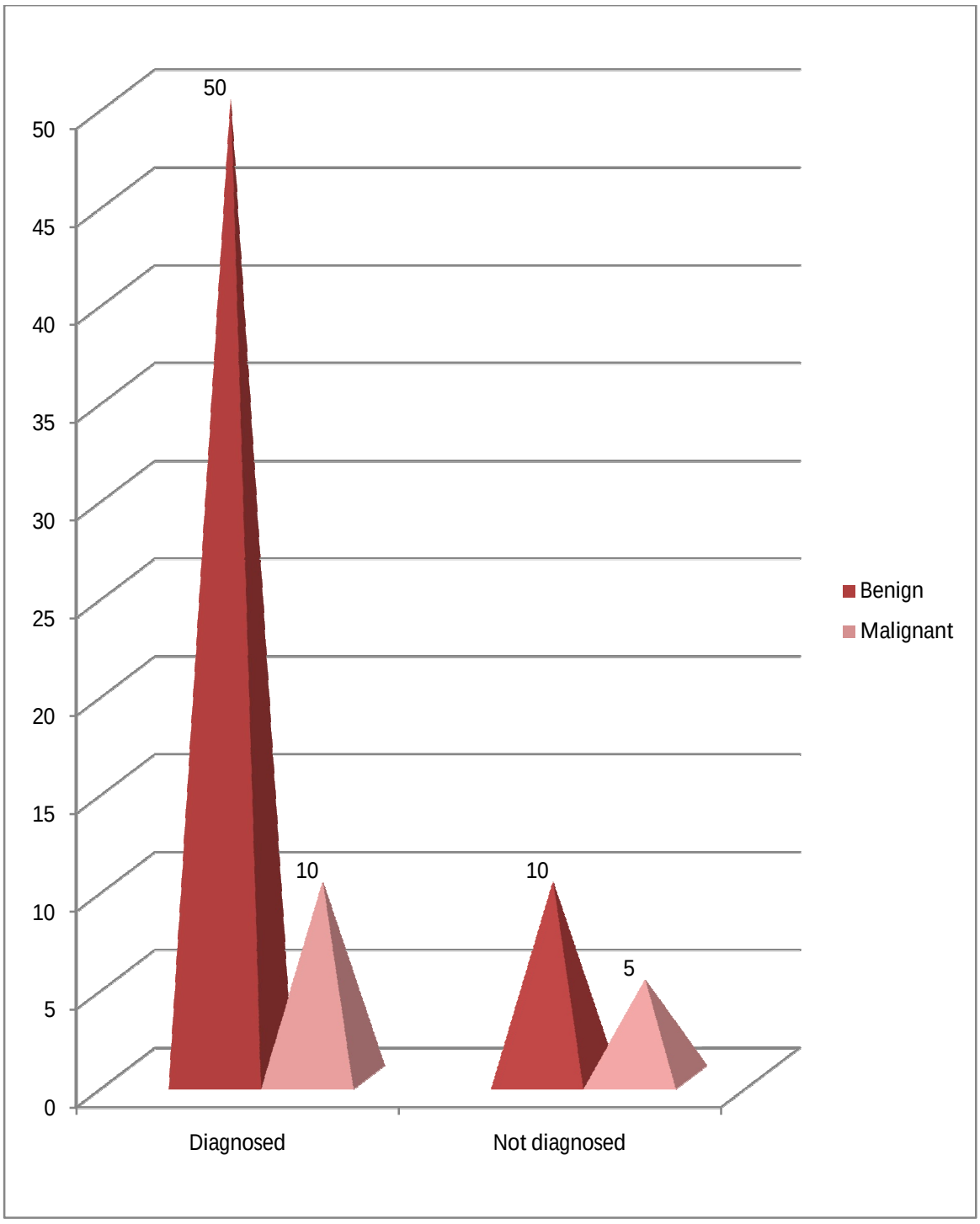
			HPE		
			0	1	Total
CA125	0	Count	50	5	55
		% within HPE	83.3%	33.3%	73.3%
		% of Total	66.7%	6.7%	73.3%
	1	Count	10	10	20
		% within HPE	16.7%	66.7%	26.7%
		% of Total	13.3%	13.3%	26.7%
	Total	Count	60	15	75
		% within HPE	100.0%	100.0%	100.0%
		% of Total	80.0%	20.0%	100.0%

From table no: 8.1 **83.3%** of benign tumours and **66.7**% of malignant tumours are diagnosed by CA 125

Table:8.2

kappa value	0.444
App.sig	0.000

BAR CHART:6



This bar chart correlates findings of CA125 and HPE

RESULTS OF CA125

Table:8.3

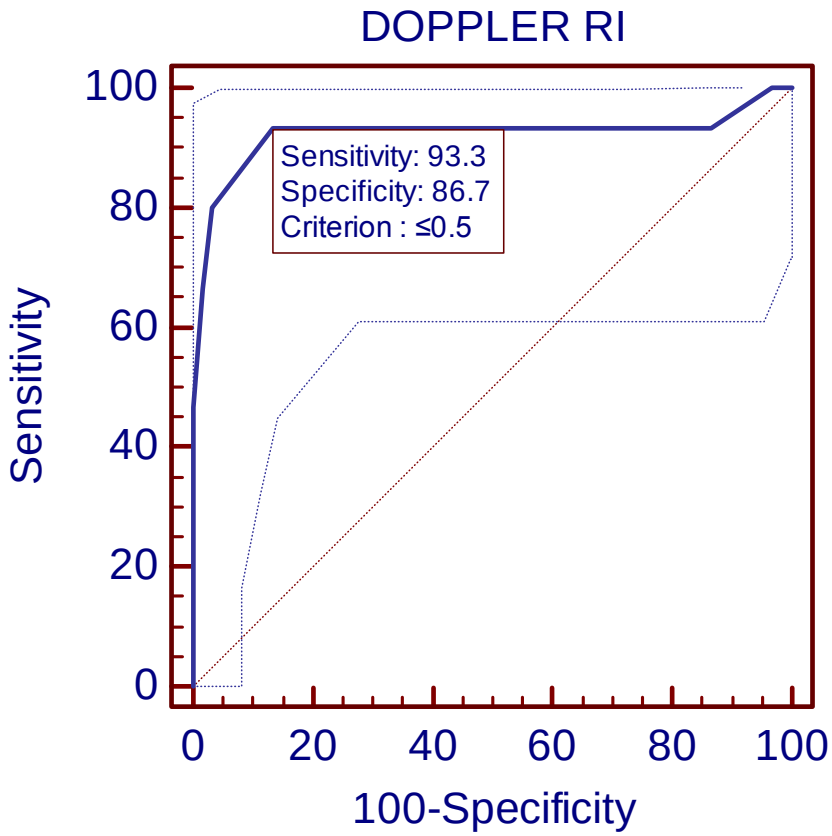
Sensitivity	66.67%
Specificity	83.33%
Positive Likelihood Ratio	4
Negative Likelihood Ratio	0.40
Disease prevalence	20%
Positive Predictive Value	50%
Negative Predictive Value	90.91%

Table : 8.3-shows results of CA125

CA125 diagnosed 50 patients as benign among 60 benign tumours and 10 patients as malignant in 15 malignant tumours.Kappa value is 0.444 which has moderate significance.from the above data,Sensitivity of CA125 is **66.67%** and specificity **is 83.33%.**

INTERPRETATION OF DOPPLER RESULTS

ROC CURVE FOR RESISTIVE INDEX



Sensitivity of resistive index when the cut off value is **0.5** gives the sensitivity and specificity is **93.3%** and **86.7%** respectively.

Area under curve is **0.922** which is statistically significant p value-**<0.0001**

Area under the ROC curve (AUC) of RESISTIVE INDEX

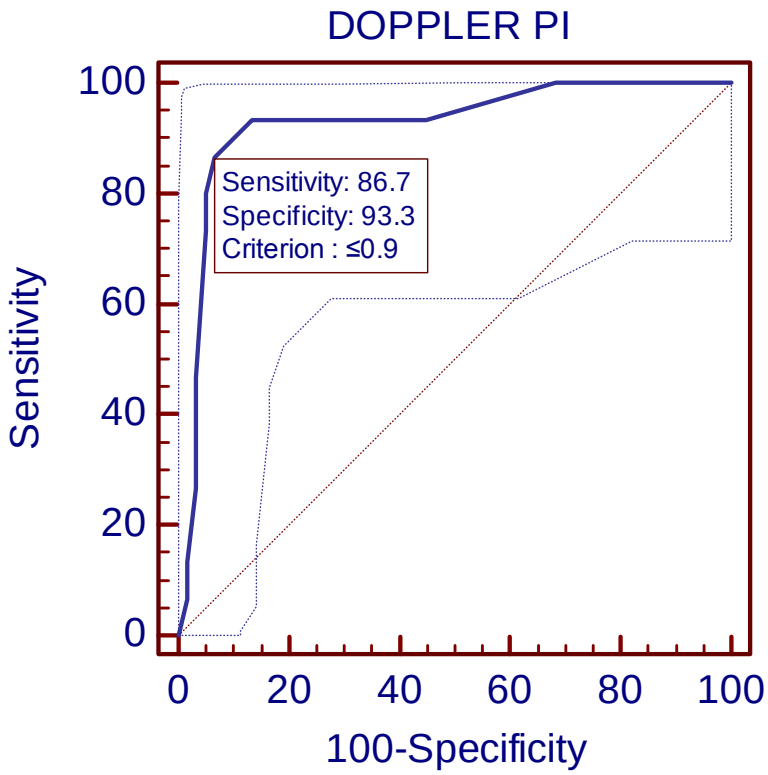
Table:9.1

Cut off value	0.5
Area under curve	0.922
Standard Error	0.0609
Significant level(Area=0.5)	<0.0001

Area under curve is **0.922** which is statistically significant

p value-**<0.0001.**

RECEIVER OPERATING CURVE FOR PULSALITY INDEX



With the PI of **0.9** the sensitivity and specificity is **86.7 %and 93.3%** respectively

Area under curve is **0.925** which is statistically significant p value<**0.0001**

Area under the ROC curve (AUC) of PULSALITY INDEX

Table:9.2

Cut off value for PI	0.9
Area under the ROC curve (AUC	0.925
Standard Error	0.0413
Significance level P (Area=0.5	<0.0001

Area under curve is **0.925** which is statistically significant

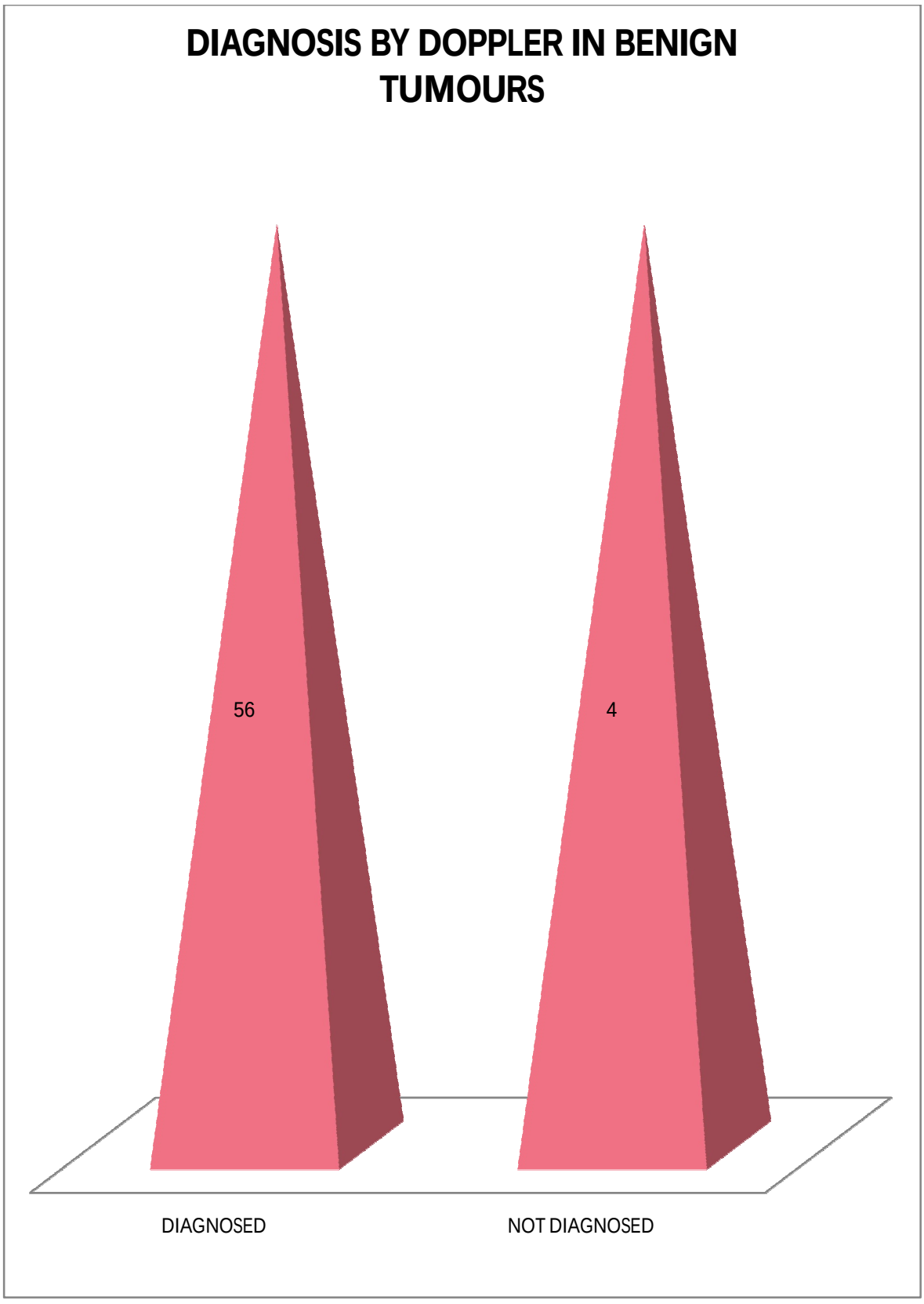
p value **<0.0001**

INTERPRETATION OF DOPPLER WITH HISTOPATHOLOGY

TABLE :10.1

			HPE		
			Benign	Malignant	Total
DOPPLER	Benign	Count	56	1	57
		% within HPE	93.3%	6.7%	76.0%
		% of Total	74.7%	1.3%	76.0%
	Malignant	Count	4	14	18
		% within HPE	6.7%	93.3%	24.0%
		% of Total	5.3%	18.7%	24.0%
	Total	Count	60	15	75
		% within HPE	100.0%	100.0%	100.0%
		% of Total	80.0%	20.0%	100.0%

Bar chart: 7


DIAGNOSIS BY DOPPLER IN BENIGN TUMOURS
56
4
DIAGNOSED
NOT DIAGNOSED

Barchart: 8

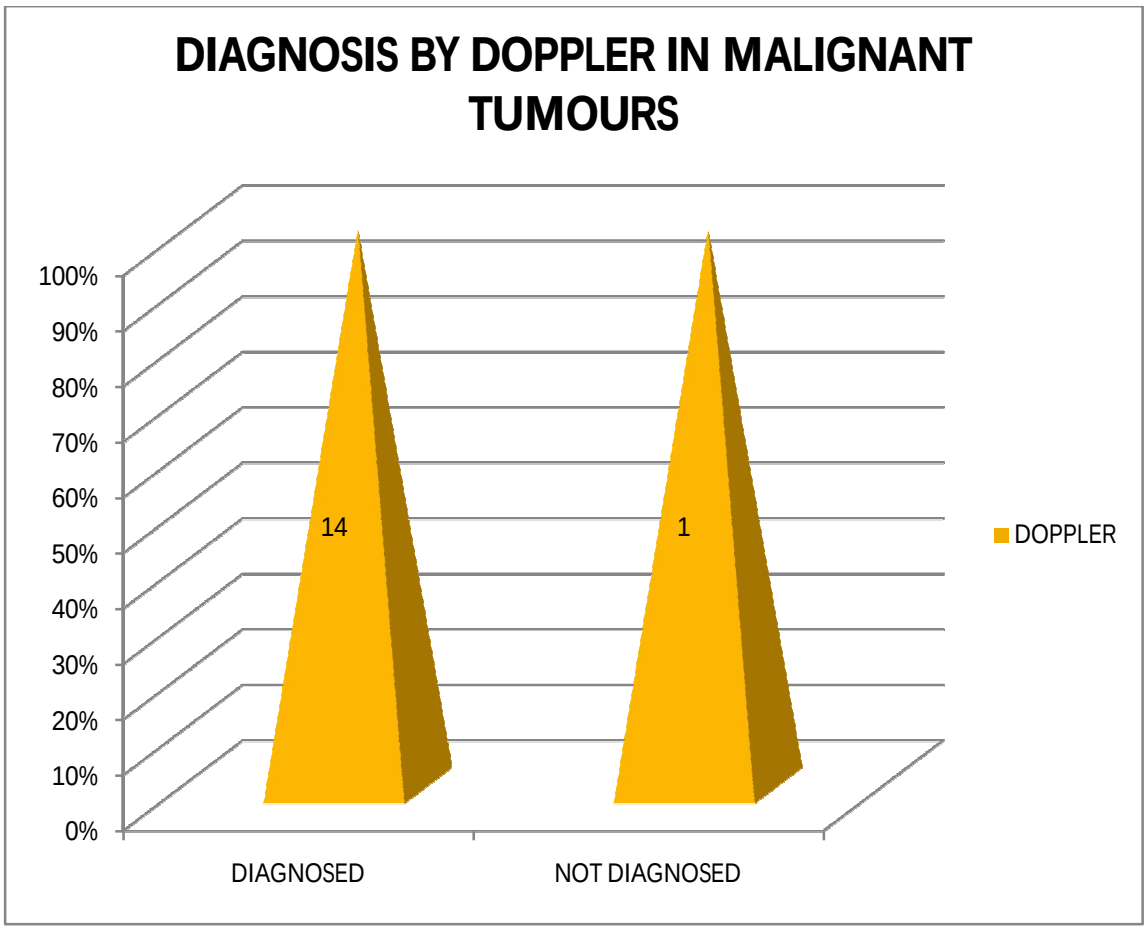
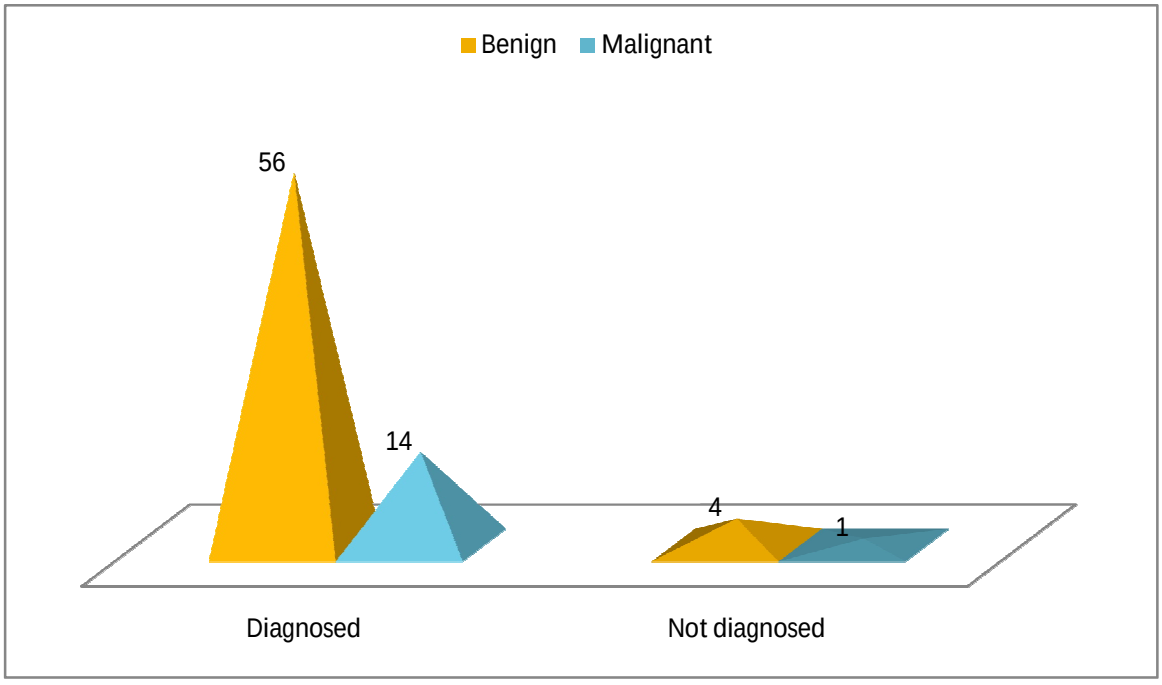

DIAGNOSIS BY DOPPLER IN MALIGNANT TUMOURS
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
14
1
DIAGNOSED
NOT DIAGNOSED
DOPPLER

Table 10.2

kappa measure of agreement	0.806
Mcnemar chi-square test (Exact sig-2 sided)	0.375
N	75

This bar chart correlates Doppler detection of malignancy with HPE



Doppler accurately diagnosed **93.3% of benign tumours** and **93.3% of malignant tumours.**

RESULTS OF DOPPLER

Sensitivity	93.33%
Specificity	93.33%
Positive Predictive Value	77.78%
Negative Predictive Value	98.25%
Diagnostic Accuracy	93.33%

from the above data,with taking RI and PI together the sensitivity and specificity of colour Doppler **93.3%**and **93.3**% respectively.Diagnostic accuracy of colour Doppler is 93.3%.

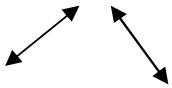
DISCUSSION

The diagnosis of malignant ovarian tumours are utmost important to decrease the mortality and morbidity of patients. Hence the aim of the study is to evaluate the accuracy of colour Doppler in diagnosing benign and malignant ovarian tumours against gold standard histopathology.

The present study included a study group of 75 patients,who were planned for surgery were selected and all diagnostic modalities were done. Colour Doppler ultrasound done and resistive and pulsality index were calculated . Results was compared with the histopathology. We didn't get any case of fallopian tube mass.

The results were compared with the other studies which were already performed and discussed as follows.

Out of 75 cases



MALIGNANT(15) (60) BENIGN

Age group in which the malignancy is most common are studied. Epithelial ovarian cancers are most common in women who are over 50 years of age, and who are post-menopausal. Study done by ***national cancer intelligence network in 2009*** reported that Epithelial tumours are the most common morphological group of ovarian cancer, accounting for 32% of all cases in 2009, and is particularly common in women aged **45-74** at diagnosis. Borderline accounting for 14% of cases and is most common in women aged under 45. Sex cord-stromal or germ cell tumours are most common in women under the age of 35, particularly in girls and young women in their 20's.

Our study reported that 60% of Benign tumours are more common in age group of 15-40yrs and 66.7% of Malignant tumours are common in age group of **41-60yrs**. In malignant tumours epithelial tumours are more common in **41-60yrs** and germ Cell tumours are common in **20-30yrs**.

In most of the studies conducted by ***kurjak et al*** [23,25]***,lancet et al*** described that malignancy is most common in postmenopausal womens.our study reported that 7 out of 15 malignancy patients constituting about **46.7%** are postmenopausal.

Women with family history of ovarian cancer in the mother and sister have 3 to 4 times the risk of ovarian cancer than women without a family history. Our study reported that 8 among the 15 malignant patients constituting **53.3%,** have history of malignancy either in the mother, sister or close relatives.

Conventional ultrasonography is widely used in diagnosis of ovarian masses by the morphological pattern of the tumors but it lacks sensitivity in distinguishing benign from malignant lesions.[1] ***Van Nagell et al*** [49]. screened 25,327 women using Transvaginal ultrasonography , reported a sensitivity of 85% for all stages of disease with a specificity of 98.7% and a PPV of 14%.

In our study the Sensitivity and specificity of ultrasonography is **67%** and 82% respectively.To conclude , ultrasound have low specificity and sensitivity compared to colour Doppler study.

Studies conducted by ***kitajima k,senda k*** in 2011 reported that sensitivity, specificity and accuracy of CT scanning to detect malignant or borderline tumors were 82.4, 76.9, and 81.1%, respectively.

In our study ,CT abdomen and pelvis have sensitivity of 80 % and specificity of 85% .

The ***Shizuoka Cohort Study of Ovarian Cancer*** Screening randomly assigned women and studied role of CA125 reported the sensitivity of 56 %and specificity of 93%in stage 1 disease.in advanced stage it is 73 %and 94.4% respectively.

In our study CA 125 has got sensitivity of **66.7%** and specificity of 83.3% ***Kurjak*** [25]and colleague reported that resistance index less than 0.4 was highly sensitive and specific in predicting ovarian malignancy . Using regression analysis, both ***Tailor and coworkers*** and ***Schelling*** and associates have found that colour Doppler have high sensitivity and specificity in diagnosing malignant tumours.

Timor-Tritsch et al (1993) [45] reported the RI value of 0.4 had sensitivity 93.8% and specificity of 98.7% . Considering RI value of 0.5 as the cut-off point, in our study the sensitivity and specificity are 93.3%and 86.7% respectively.

Cut-off level of PI value 0.9, giving the sensitivity and specificity of 86.7%and 93.3% respectively, was similar to the study of ***Sengoku et al (1994)*** [42] reported sensitivity and specificity of 81.3% and 91.7% respectively.

Study conducted by ***Theeretongsong*** [46] in march 2008 found that among 306 cases 191 were benign and 115 were malignant.The sensitivity and specificity of the resistive index were 94.8 % and 93.2% respectively with the cut off value of 0.4 and the values for pulsatility index were 93.0% and 92.7% with the cut off value of 1.2.

The summary of research by receiver operating characteristic (SROC) methodology first described by ***Moses et al.*** [29] and ***Irwig et al*** [19] was applied.

Area under curve for RI is 0.922 if the cut off value is <0.5with the 95% confidence interval.And the p value is <0.0001.

AArea under curve for PI is 0.945 if the cut off value is <0.9 with the 95% confidence interval.and the p value is <.0001

METHODS USED IN STATISTICS

The accuracy of the test depends on how well the test separates the group being tested into those with and without the disease in question. Accuracy is measured by the area under the ROC curve. An area of 1 represents a perfect test; an area of .5 represents a worthless test. A rough guide for classifying the accuracy of a diagnostic test is the traditional academic point system:

ROC CURVE

- .90-1 = excellent (A)
- .80-.90 = good (B)
- .70-.80 = fair (C)
- .60-.70 = poor (D)
- .50-.60 = fail (F)

KAPPA AGREEMENT.

Creates a classification table, from raw data in the spreadsheet, for two observers and calculates an inter-rater agreement statistic (***Kappa***) to evaluate the agreement between two classifications on ordinal or nominal scales (***Cohen, 1960; Fleiss et al., 2003***).

Value of *K*	Strength of agreement
< 0.20	Poor
0.21 - 0.40	Fair
0.41 - 0.60	Moderate
0.61 - 0.80	Good
0.81 - 1.00	Very good

SUMMARY

This study concludes that colour Doppler has more sensitivity and specificity in differentiating benign and malignant tumours when compared to other diagnostic modalities.

This study also reveals that

- **Benign tumours** are most common in **15-40 yrs** and **malignant tumours** are most common in **41-60 yrs**.
- Epithelial tumours are most common in postmenopausal patients about 70%.Germ cell tumours are common in premenopausal patients.
- Family history of malignancy correlate well with the malignancy rate.
- Ultrasonography has sensitivity and specificity **66.7%** and **81%** respectively

- CT Abdomen and pelvis has sensitivity and specificity of **80%** and **85%** respectively

- Ca125 has sensitivity and specificity of **66.67**% and **83.3**% Respectively

- Resistive index has sensitivity and specificity of 93.3% and specificity of 86.7% respectively

- Pulsality Index has sensitivity and specificity of 86% and 94% respectively

- With considering both RI and PI the Doppler has sensitivity and specificity are 93.3% and 93% respectively.

CONCLUSION

Ovarian tumours are most common malignant tumour among gynaecological cancer.ovarian cancer is a hidden form of gynaecological malignancy which usually reveales itself in a stage where the spread has occured extensively.

Early detection and prompt treatment is very important. Early diagnosis will increase the survival rate of the cancer patients.[33] Use of colour Doppler sonography as a diagnostic and as a screening tool for ovarian cancer is the best choice recommended.This study substantiates and confirms this recommendation.

Its being a non invasive diagnostic modality it can be easily performed without much difficulty without causing discomfort to patients.Increasing availability of colour Doppler along with ultrasonography at reasonable costs has made it affordable even to the poor socioeconomic status.

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PROFORMA

NAME

AGE

ADDRESS

OP/IP NO

MARITAL HISTORY

MENSTURAL HISTORY

OBSTETRIC HISTORY

PAST HISTORY OF ADNEXAL MASS REMOVAL

SPECIFIC COMPLAINTS

GENERAL EXAMINATION

HT /WT

VITALS

CVS:

RS:

PER ABDOMEN EXAMINATION:

PER VAGINAL EXAMINATION:

INVESTIGATIONS

1.CBC

2.RFT

3.URINE ROUTINE

4.VDRL

5.HIV

6.HBSAG

7.USG(TVS/TAS)

8.CT ABDOMEN AND PELVIS

9.CA125

10.COLOUR DOPPLER

11.HISTOPATHOLOGY

SIGNATURE OF INVESTIGATOR: SIGNATURE OF GUIDE:

INFORMATION SHEET

We are conducting a study on **"TO EVALUATE THE EFFICACY OF COLOUR DOPPLER IN DIAGNOSING ADNEXAL MASSES AT GOVERNMENT KILPAUK MEDICAL COLLEGE AND HOSPITAL, CHENNAI"** Among patients attending Kilpauk medical college Hospital, Chennai and for that your specimen may be valuable to us.

The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.

The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of Investigator Signature of Participant

Date :

Place :

PATIENT CONSENT FORM

Study Detail	:	"To evaluate the Efficacy of Colour Doppler in Diagnosing Adnexal Masses at Government Kilpauk Medical College and Hospital, Chennai"
Study Centre	:	Kilpauk medical college Hospital, Chennai.
Patient's Name	:	
Patient's Age	:	
Identification Number	:	

Patient may check (√) these boxes

a) I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction. ☐

b) I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected. ☐

c) I understand that sponsor of the clinical study, others working on the sponsor's behalf, the ethical committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study. ☐

d) I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms. ☐

e) I hereby consent to participate in this study. ☐

f) I hereby give permission to undergo complete clinical examination and hematological tests. ☐

Signature/thumb impression

Patient's Name and Address:

Signature of Investigator

Study Investigator's Name:

Dr.S.KALAIVANI

S.NO.	NAME	AGE	IP.NO	AGE GROUP	MENOPAUSAL AGE	H/O MALIGNANCY	USG	CA125	CA125	CT	DOPPLER	BENIGN-0	DOPPLER	BENIGN-0	DOPPLER	HPE	HPE	BENIGN TUMOURS	MALIGNANT
				15-40-0	PRE-0	NO-0	BENIGN-0	<35	<35-0	BENIGN-0	RI	MALIGNANT-1	PI	MALIGNANT-1			BENIGN-0		
				41-60-1	POST-1	YES-1	MALIGNANT-1	>35	>35-1	MALIGNANT-1							MALIGNANT-1		
1	Geetha	42	1323587	1	0	0	0	18	0	0	0.9	0	1.2	0	0	SEROUS CYSTADENOMA	0	0	
2	Shanthi	41	1319662	1	0	0	1	28	0	1	0.2	1	0.7	1	1	GRANULOSA CELL TUMOUR	1		3
3	Jamuna	46	1324657	1	0	0	0	15.2	0	0	0.5	0	1.8	0	0	MUCINOUS CYST ADENOMA	0	1	
4	Abitha	16	1233453	0	0	0	0	32	0	0	0.7	0	1.4	0	0	MUCINOUS CYST ADENOMA	0	1	
5	Susheela	31	1324567	0	1	0	0	6.34	0	0	0.8	0	1.3	0	0	SEROUS CYSTADENOMA	0	0	
6	Aruna	34	1308183	0	0	0	0	17	0	0	0.9	0	1	0	0	MUCINOUS CYSTADENOMA	0	1	
7	Premalatha	32	1312456	0	1	0	1	19	0	1	0.2	1	0.8	1	1	DYSGERMINOMA	1		2
8	Ludhina	48	1342564	1	0	0	0	12.4	0	0	0.9	0	1.4	0	0	SEROUS CYSTADENOMA	0	0	
9	Prescika	30	1302346	0	0	0	0	8.9	0	0	1.2	0	1.5	0	0	MUCINOUS CYSTADENOMA	0	1	
10	Ansaribee	58	1314245	1	1	0	0	3.25	0	1	0.5	0	0.3	1	1	MUCINOUS CYSTADENOMA	0	0	
11	Anbarasi	34	1320675	0	0	0	1	45.9	1	0	0.9	0	1.2	0	0	SEROUS CYSTADENOMA	0	0	
12	palanal	52	124434	1	1	0	1	89.2	1	1	0.2	1	0.9	1	1	MUCINOUS CYSTADENOCARCIN	1		1

			3												OMA			
13	Kamatchi	44	1234563	1	0	0	0	23.4	0	1	0.5	1	0.9	1	1	MUCINOUS CYSTADENOMA	0	1	
14	Rajeshwari	43	1256547	1	1	0	0	12.3	0	0	0.9	0	1.6	0	0	KERATOTIC CYST	0	3	
15	Govindammal	50	1233543	1	1	0	1	42.3	1	0	0.5	0	1.2	0	0	MUCINOUS CYSTADENOMA	0	1	
16	Amul	36	1305117	0	1	0	0	8.23	0	0	0.7	0	1.9	0	0	MUCINOUS CYSTADENOMA	0	1	
17	Kirubha	45	1235456	1	1	0	1	79	1	1	0.3	1	0.7	1	1	SEROUS CYSTADENOMA	0	0	
18	Arputhamary	45	1233546	1	0	1	0	29	0	0	0.8	0	1.9	0	0	SEROUS CYSTADENOMA	0	0	
19	Selvakumari	34	1300541	0	1	0	1	23	0	1	1.3	0	1.8	0	0	MUCINOUS CYSTADENOMA	0	1	
20	Vijaya	49	1301253	1	0	0	1	16	0	1	0.1	1	0.5	1	1	GRANULOSA CELL TUMOUR	1		3
21	Sangeetha	43	1200517	1	0	1	0	11.2	0	0	0.5	0	1	0	0	MUCINOUS CYSTADENOMA	0	1	
22	Dharani	46	1204567	1	0	0	1	12.5	0	0	0.6	0	1.1	0	0	KERATOTIC CYST	0	3	
23	Lalitha	33	1214456	0	0	0	1	37.2	0	0	0.6	0	1.2	0	0	SEROUS CYSTADENOMA	0	0	
24	annamal	52	1304451	1	1	0	1	101.3	1	0	0.2	1	0.6	1	1	MUCINOUS CYSTADENOCARCINOMA	1		1
25	Lakshmi	41	1307789	1	0	0	0	12.3	0	0	0.8	0	1.2	0	0	FOLLICULAR CYST	0	4	
26	Renukadevi	28	1339877	0	0	0	0	56	1	1	0.2	1	0.5	1	1	DYSGERMINOMA	1		2
27	Rathna	3	131	0	0	0	1	67.	1	0	0.6	0	1.4	0	0	SEROUS	0	0	

		2	5666					8								CYSTADENOMA			
28	Chitra	52	1300203	1	0	1	0	45.6	1	1	1.2	0	1.4	0	0	MUCINOUS CYSTADENOMA	0	1	
29	Kuppammal	43	1332480	1	0	0	0	12.3	0	0	0.7	0	1.2	0	0	SEROUS CYSTADENOMA	0	0	
30	Latha	31	1324556	0	1	0	0	23.4	0	0	1.1	0	1.3	0	0	SEROUS CYSTADENOMA	0	0	
31	chinnathal	34	1307888	0	1	0	1	45.6	1	1	1.2	0	1.3	0	0	MUCINOUS CYSTADENOMA	0	1	
32	Rakkamma	35	1309080	0	0	0	0	12	0	0	1.2	0	1.4	0	0	DERMOID CYST	0	2	
33	Revathy	30	1302030	0	0	0	0	13.4	0	0	0.7	0	1.4	0	0	SEROUS CYSTADENOMA	0	0	
34	Varalakshmi	41	1314565	1	0	0	0	56.8	1	0	0.9	0	1.2	0	0	DERMOID CYST	0	2	
35	Sasikala	31	1315678	0	0	0	0	4.67	0	0	0.8	0	1.3	0	0	SEROUS CYSTADENOMA	0	0	
36	Meenatchi	32	1310390	0	0	0	0	12.7	0	0	0.7	0	1.4	0	0	MUCINOUS CYSTADENOMA	0	1	
37	Ammu	50	1309876	1	0	0	0	38	1	0	0.8	0	1.1	0	0	KERATOTIC CYST	0	3	
38	Jayanthi	32	1302984	0	0	0	0	12.1	0	0	0.8	0	1.2	0	0	DERMOID CYST	0	2	
39	Saraswathi	57	1314567	1	0	0	1	56.8	1	1	0.3	1	0.7	1	1	MUCINOUS CYSTADENOCARCINOMA	1		1
40	Bargath	41	1324556	1	0	1	0	3.56	0	0	0.7	0	1.3	0	0	MUCINOUS CYSTADENOMA	0	1	
41	Shanthi	39	1324134	0	0	0	0	7.8	0	0	0.8	0	1.2	0	0	DERMOID CYST	0	2	

42	muthayi	41	1324566	1	0	0	0	4.5	0	0	0.5	0	1.3	0	0	SEROUS CYSTADENOMA	0	0	
43	Umaprakash	40	1302993	0	0	0	0	23.4	0	0	1.3	0	1.3	0	0	SEROUS CYSTADENOMA	0	0	
44	Vinitha	32	1320099	0	0	1	0	8.9	0	0	0.9	0	1.4	0	0	MUCINOUS CYSTADENOMA	0	1	
45	Rebecca	39	1318892	0	0	0	0	10.2	0	0	0.8	0	1.1	0	0	DERMOID CYST	0	2	
46	vasanthammal	42	1323667	1	0	0	0	64.7	1	1	0.5	0	1	0	1	IMMATURE TERATOMA	1		4
47	Rajeswari	40	1312456	0	0	0	0	32.6	0	0	0.8	0	1.2	0	0	SEROUS CYSTADENOMA	0	0	
48	Maheswari	34	1325690	0	1	1	0	31.5	0	0	0.9	0	1.3	0	0	SEROUS CYSTADENOMA	0	0	
49	Yogalakshmi	23	1312456	0	0	0	1	56.8	1	1	0.5	0	0.7	1	1	MUCINOUS CYSTADENOCARCINOMA	1		1
50	Abitha	19	1312455	0	0	1	0	32.6	0	0	0.9	0	1.2	0	0	MUCINOUS CYSTADENOMA	0	1	
51	Amul	48	1324455	1	0	0	0	23.6	0	0	0.7	0	1.4	0	0	SEROUS CYSTADENOMA	0	0	
52	Janaki	28	1314589	0	0	0	0	45.6	1	1	1.2	0	1.3	0	0	DYSGERMINOMA	1		2
53	Nazreen	46	1318909	0	1	0	1	57	1	1	0.3	1	0.4	1	1	SEROUS CYSTADENOCARCINOMA	1		0
54	pitchaimuthu	30	1324563	0	0	1	0	32	0	0	0.8	0	1.5	0	0	SEROUS CYSTADENOMA	0	0	
55	Panjavarnam	46	1324590	1	0	0	1	37.9	1	1	0.7	0	1	0	0	MUCINOUS CYSTADENOMA	0	1	
56	Ranjani	32	1332789	0	0	0	0	24	0	0	0.9	0	1.2	0	0	SEROUS CYSTADENOMA	0	0	

57	kunjamma	48	1333890	1	1	0	1	12.4	0	1	0.1	1	0.6	1	1	SEROUS CYSTADENOCARNOMA	1		0
58	Uma	30	1312456	0	0	0	0	30.8	0	0	0.6	0	1.3	0	0	SEROUS CYSTADENOMA	0	0	
59	petchiammal	46	1332345	1	0	0	0	23.5	0	0	0.9	0	1.2	0	0	FOLLICULAR CYST	0	4	
60	Mallika	41	1334256	1	0	0	0	18.5	0	0	0.9	0	1.3	0	0	DERMOID CYST	0	2	
61	Vimala	32	1324555	0	1	0	1	13	0	0	0.4	1	0.5	1	1	MUCINOUS CYSTADENOMA	0	1	
62	Rajeswari	51	1312222	1	0	0	0	14.6	0	0	0.8	0	1.2	0	0	SEROUS CYSTADENOMA	0	0	
63	Selvi	38	1323456	0	0	0	0	8.9	0	0	0.8	0	1.3	0	0	SEROUS CYSTADENOMA	0	0	
64	Dowlath	51	1324891	1	1	0	0	76.8	1	1	0.4	1	0.3	1	1	SEROUS CYSTADENOCARCINOMA	1		0
65	Palaniammal	43	1324678	1	0	0	0	3.56	0	0	0.8	0	1.3	0	0	MUCINOUS CYSTADENOMA	0	1	
66	Radhika	21	1324444	0	0	0	1	67.8	0	0	1.2	0	1.4	0	0	DERMOID CYST	0	2	
67	Subhathara	47	1332456	1	1	0	0	12.3	0	0	0.4	1	0.6	1	1	MUCINOUS CYSTADENOCARCINOMA	1		1
68	vasanthi	27	1331256	0	0	0	0	3.4	0	1	0.9	0	1.2	0	0	SEROUS CYSTADENOMA	0	0	
69	Durgadevi	36	1333324	0	0	0	0	32.4	0	0	0.8	0	1.4	0	0	DERMOID CYST	0	2	
70	Muthulakshmi	32	1334567	0	0	0	0	12.9	0	1	1.1	0	1.4	0	0	SEROUS CYSTADENOMA	0	0	
71	Visalatchi	34	1332456	0	0	0	0	13.5	0	0	1.2	0	1.3	0	0	DERMOID CYST	0	2	

72	Kaliammal	43	1326789	1	1	0	1	35.6	1	1	0.3	1	0.7	1	1	GRANULOSA CELL TUMOUR	1		3
73	ponnamal	35	1334208	0	0	0	0	25.6	0	0	0.9	0	1.3	0	0	SEROUS CYSTADENOMA	0	0	
74	prema	32	1332456	0	0	0	0	23.45	0	0	0.8	0	1.1	0	0	MUCINOUS CYSTADENOMA	0	1	
75	ambika	32	1332112	0	0	0	0	8.9	0	0	0.7	0	1	0	0	SEROUS CYSTADENOMA	0	0	
												0							

KEY TO MASTER CHART:

0-BENIGN

1-MALIGNANT

HPE-HISTOPATHOLOGY

RI-RESISTIVE INDEX

PI-PULSALITYINDEX

IN "R" COLUMN,BENIGN TUMOURS

0-SEROUS CYSTADENOMA

1-MUCINOUS CYSTADENOMA

2-DERMOID

3-KERATOTIC CYST

4-FOLLICULAR CYST

IN "S" COLUMN ,MALIGNANT TUMOURS

0-SEROUS CYATAEDNOCARCINOMA

1-MUCINOUS CYST ADENOCARCINOMA

2-DYSGERMINOMA

3-GRANULOSA CELL TUMOUR

4-MATURE TERATOMA

INSTITUTIONAL ETHICAL COMMITTEE
GOVT.KILPAUK MEDICAL COLLEGE,
CHENNAI-10
Ref.No.12117/ME-1/Ethics/2012 Dt:03.01.2013.
CERTIFICATE OF APPROVAL

The Institutional Ethical Committee of Govt. Kilpauk Medical College, Chennai reviewed and discussed the application for approval "A Study on prospective observational study in evaluating the efficacy of Doppler in diagnosing adnexal masses" for dissertation purpose submitted by Dr.S.Kalaivani, MS (O&G), PG Student, Govt. Kilpauk Medical College, Chennai

The Proposal is APPROVED.

The Institutional Ethical Committee expects to be informed about the progress of the study any Adverse Drug Reaction Occurring in the Course of the study any change in the protocol and patient information /informed consent and asks to be provided a copy of the final report.

CHAIRMAN, 21/1/13.
Ethical Committee
Govt.Kilpauk Medical College,Chennai

GOVT. KILPAUK MEDICAL COLLEGE
21 JAN 2013
Kilpauk, Chennai-10.